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Supreme Court of the United States

IMS HEALTH, INC. AND VERISPAN LLC,
Petitioners,

v.

KELLY M. AYOTTE, AS ATTORNEY GENERAL
OF THE STATE OF NEW HAMPSHIRE,
Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the First Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

For decades, publishers have acquired doctors' prescribing histories, and used the information to publish reports. Drug companies use that information to deliver information about new products to doctors. New Hampshire has made it a crime to transfer prescribing histories within the state to increase brand-name drug sales. The First Circuit held that the law does not implicate the First Amendment because it targets conduct and involves only speech with "scant societal value." Alternatively, it held that the First Amendment permits the government to "level the playing field" in communications with doctors, notwithstanding that the law in fact "may not accomplish very much."

The Questions Presented are:

1. To what extent does the First Amendment protect the acquisition, analysis, and publication of accurate factual information that is used by third parties for a commercial purpose?
2. Does the First Amendment permit such a prohibition when the government seeks to "level the playing field" by inhibiting truthful speech while simultaneously permitting the use of the identical information for communication of the state's preferred viewpoint?
3. Does the First Amendment permit such a prohibition when it is both grossly underinclusive (because it is so riddled with exceptions that it "may not accomplish very much") and overinclusive (because it inhibits even communication that the state acknowledges benefits public health)?

RULE 29.6 DISCLOSURES

IMS Health, Inc. has no parent corporation and no publicly owned corporation owns 10 percent or more of its stock. Verispan, LLC is wholly owned by SDI Health LLC and no publicly owned corporation owns 10 percent or more of its stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners IMS Health, Inc. and Verispan LLC respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the First Circuit in this case.

OPINIONS BELOW

The court of appeals' opinion (Pet. App. 1) is published at 550 F.3d 42. The district court's opinion (Pet. App. 152) is published at 490 F. Supp. 2d 163.

JURISDICTION

The First Circuit denied timely petitions for rehearing on January 14, 2009. Pet. App. 201. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS

The First Amendment to the Constitution of the United States provides:

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

The Appendix reproduces the relevant statutory provisions.

STATEMENT OF THE CASE

New Hampshire law makes it a crime to transfer or use within the state information regarding a doctor's prescribing history for the purpose of increasing the sales of drugs. The district court held that the law violates the First Amendment because the government cannot quarantine doctors from truthful speech about the merits of prescription drugs. The First Circuit reversed, holding that the statute does not implicate the First Amendment and, alternatively, that the government may seek to obstruct speech that it believes will drive up the cost of health care, although it acknowledged that this statute may not substantially advance that interest.

1. Petitioners IMS Health and Verispan are among the world's largest publishers of information, research, and analysis for the health care and pharmaceutical industries. Among other things, petitioners collect, assess, and publish information on physicians' prescribing histories. Petitioners produce reports identifying the physicians who regularly treat particular conditions or prescribe specific prescription medications, as well as those who have shown themselves most likely to adopt new treatments. Petitioners acquire information about prescriptions principally from the centralized data centers of pharmacy chains and pharmacy software vendors, which in turn receive it in the ordinary course of business from the local pharmacies that fill prescriptions.

To protect personal privacy, petitioners do not collect information that would identify the individual patients who submitted the prescriptions. In

addition, petitioners comply with a program of the American Medical Association that permits doctors to restrict use of information about their prescribing activity by pharmaceutical sales representatives.

Petitioners' principal commercial clients are pharmaceutical companies. Those companies use petitioners' reports to engage in "detailing" - discussions in which (assuming a physician wants to meet with the drug company's representative) they provide the physician with information regarding the medical benefits of their products and, in turn, learn from doctors' experiences with various treatments. The revenue generated by petitioners' relationship with pharmaceutical companies allows petitioners to also provide prescription history data at little or no cost to an array of other organizations for public health purposes.

2. The federal government prohibits any drug promotion that is false, misleading, or that lacks a "fair balance between information relating to side effects and contra-indications and information relating to effectiveness." 21 C.F.R. § 202.1(e)(5)-(6). *See generally* 21 U.S.C. §§ 332-337. Some states nonetheless have grown hostile to the practice of pharmaceutical detailing, on the theory that it drives up the use of brand-name drugs and, in turn, the cost of health care. They have adopted two regulatory responses.

First, states have developed so-called "counter detailing" programs, under which the government uses prescription history data (generally secured from Medicaid and Medicare claims records) to identify and contact doctors to persuade them to prescribe less-expensive medications. For example,

New Hampshire is deploying an "evidence-based prescription drug education program" to utilize one-on-one communications with health care providers to encourage the prescription of less expensive generic drugs. N.H. Rev. Stat. § 126-A:5, XVII. New Hampshire also authorizes "formulary compliance" programs, through which insurance companies and state health agencies use prescription history information to persuade or require doctors to prescribe generic alternatives or cheaper brand-name products. N.H. Rev. Stat. § 318:47-f.

Second, states have sought to make detailing more costly and inefficient by prohibiting the transfer or use of prescription history information to increase drug sales. New Hampshire's "Prescription Information Law" (PIL) makes it a crime for a pharmacy, insurer, or "similar entit[y]" to "transfer" or "use" prescription data for the purpose of "any activity that could be used to influence sales or market share of a pharmaceutical product." N.H. Rev. Stat. § 318:47-f.

As authoritatively construed by the First Circuit, the PIL prohibits only the transfer of prescription data (a) within the State of New Hampshire (b) for the purpose of influencing drug sales. Pet. App. 13, 49. The statute has no application to data that is initially transferred from an in-state pharmacy to an out-of-state data center of a pharmacy chain or insurance company in the "routine" course of the pharmacy's business. *Id.* 50. Petitioners, the drug chains, and drug companies all have their operations outside of New Hampshire. As a practical matter, the statute therefore applies only to prescription data that originates from the limited number of non-chain

pharmacies in New Hampshire, because those small entities generally do not otherwise make use of out-of-state data centers. *Id.*

3. In 2006, petitioners brought this suit in federal district court alleging that the PIL violates, *inter alia*, the First Amendment. After receiving extensive evidentiary submissions and holding a trial on the merits, the district court agreed and issued a permanent injunction for the reasons set forth in a lengthy opinion. Pet. App. 152-199.

The district court recognized that petitioners have standing to challenge the PIL because the statute directly regulates petitioners' acquisition, analysis, and publication of covered prescription history data. Pet. App. 176 n.9. To the extent petitioners' speech was not directly prohibited, their acquisition and publication of that data would subject them to criminal liability for conspiracy to violate the PIL. *Id.*

The district court held that the PIL regulates speech because the First Amendment protects the transmission of factual information, not merely advocacy or expression. Pet. App. 177. The court further reasoned that the PIL is subject to intermediate scrutiny as a regulation of commercial speech, though it recognized that existing precedent "is unclear as to how commercial speech is defined." *Id.* 180.

In assessing the statute's constitutionality, the district court determined from the trial record that the PIL does not directly further an important governmental interest, reasoning that it would be inappropriate to defer to New Hampshire's judgment to enact the statute. Pet. App. 183 n.12. The district

court recognized that, under this Court's precedents, the State's paternalistic attempt to inhibit the free flow of information between drug companies and doctors does not amount to a significant governmental interest, particularly given the sophistication of trained physicians in evaluating "truthful and non-misleading marketing information." *Id.* 193.

The district court concluded that the PIL is invalid for the additional reason that it is not properly tailored to advance the State's interest in promoting public health and lowering drug costs. By "impos[ing] a sweeping ban on the use of prescriber-identifiable information to enhance the effectiveness and efficiency of all detailing," the statute applies even when "detailing serves the state's interest in public health by *promoting* efficacious treatments." Pet. App. 194 (emphases added). Further, the State has available to it measures to provide "competing information that will help health care providers balance and place in context the sales messages that detailers deliver." *Id.* 195.

4. On respondent's appeal, the First Circuit reviewed the district court's findings *de novo* and reversed. Pet. App. 12; *id.* 1-51. The court deemed the PIL to be entirely outside "the proscriptions of the First Amendment," reasoning that the statute principally regulates conduct and that the communication of prescription data has "scant societal value. *Id.* 22-23 & n.6. On that view, the information exchanges prohibited by the PIL are indistinguishable from "obscene" speech and "fighting words." *Id.* 20, 22. Though the court of appeals acknowledged that the dissemination of factual

information has been held to be protected by the First Amendment, it rejected that conclusion in "a situation in which information itself has become a commodity." *Id.* 22-23. In that circumstance, the court concluded, the transfer of information is entitled to no greater First Amendment protection than a shipment "of, say, beef jerky." *Id.* 23.

The First Circuit held, in the alternative, that the PIL survives intermediate scrutiny as a restriction on commercial speech. Pet. App. 27-41. The court of appeals recognized this Court's conclusion that the category of lesser-protected commercial speech is limited to statements proposing a commercial transaction. *Id.* 27 (citing *Board of Trustees v. Fox*, 492 U.S. 469, 473-74 (1989)). But it elected to "reject" that narrow definition and instead apply its own circuit precedent, which more broadly defines commercial speech as all communication relating to the speaker's commercial interests. *Id.*

The court of appeals accepted that pharmaceutical companies use prescription history data to identify the audience for their speech and to tailor a truthful message regarding the health benefits of their products. But in its view, the government may "level the playing field" by limiting the drug companies' communication in order to "improve the quality" of their discussions. *Id.* 12, 25-26.

The First Circuit refused to consider whether that interest rests on the impermissible, paternalistic assertion of the power to inhibit truthful communication. According to the majority, petitioners may not "assert the First Amendment rights" of "detailers to use prescriber-identifiable

information in communicating face-to-face with physicians, nor can they assert the rights of physicians to receive that information during such interactions." Pet. App. 13-14.

The court of appeals also found that the State had established that the PIL sufficiently advances its asserted interest. It characterized the State's proof that the PIL would lower health care costs as "not overwhelming," and indeed recognized that "there was no direct evidence on that point." Pet. App. 33. Particularly given that New Hampshire was the first state to adopt such a statute, the "evidence" that would establish the State's asserted interest "simply does not exist." *Id.* 36. But the court of appeals concluded that "this is more a matter of policy than of prediction" (*id.* 35), so that the appropriate course was to "defer to the New Hampshire legislature" (*id.* 37). In its view, "[a] state need not go beyond the demands of common sense to show that a statute promises directly to advance an identified governmental interest." *Id.* 29.

The First Circuit moreover stated that it could not identify "an alternative to the Prescription Information Law that promises to achieve the goals of the law without restricting speech." Pet. App. 41. The court of appeals recognized that New Hampshire and third parties could engage in counter-speech to persuade doctors not to prescribe expensive brand-name drugs. But the First Circuit read this Court's decision in *Posadas de P.R. Associates v. Tourism Co.*, 478 U.S. 328 (1986), to hold that such an effort was not required by the First Amendment. Pet. App. 40.

The court of appeals also recognized that the statute – which it construed to prohibit only *in-state*

transfers and uses of data – “permits the routine transfer of data to out-of-state facilities where it can then be aggregated and sold legally to others.” Pet. App. 50. Because pharmaceutical and insurance data centers, petitioners’ facilities, and drug companies are all located outside of New Hampshire, the statute thus only applies to the limited category of data transfers from New Hampshire to out-of-state facilities for the specific purpose of facilitating drug sales. Because “most prescriber-identifiable data leaves New Hampshire in [the] permissible manner” of routine transfers (*id.* 145 (separate opinion of Lipez, J.)), the court of appeals recognized that the statute “may not accomplish very much” (*id.* 50 (majority opinion)). But the First Circuit concluded that a state may adopt such a measure as a “prophylactic” protection against the further non-routine dissemination of prescription history data. *Id.*

Judge Lipez concurred in part and dissented in part. Pet. App. 51-151. In his view, the PIL regulates speech and is subject to First Amendment scrutiny because “the State targeted, albeit indirectly, the speech of the detailers.” *Id.* 96. He nonetheless concluded that the statute survives intermediate scrutiny as a regulation of commercial speech because at trial the State introduced sufficient evidence that detailing increases drug costs. *Id.* 121. Further, in his view, the PIL is not overbroad, because it only inhibits detailing, while still permitting other forms of pharmaceutical marketing. *Id.* 131. Rather than reversing the district court, however, Judge Lipez would have remanded to permit the district court to decide in the first instance

the extent to which the statute applies to routine transfers of prescription information outside of New Hampshire. *Id.* 142.

5. The First Circuit subsequently denied rehearing and rehearing en banc. Pet. App. 201.

REASONS FOR GRANTING THE WRIT

The First Circuit's decision permits the government to prohibit a class of speech – the evaluation and publication of important factual information – that is one of “the top ten emerging fields in today’s technological world.” Tal J. Zarsky, *“Mine Your Own Business!”: Making the Case for the Implications of the Data Mining of Personal Information in the Forum of Public Opinion*, 5 Yale J. L. & Tech. 4 (2003). This speech has “entered a golden age, whether being used to set ad prices, find new drugs more quickly or fine-tune financial models.” Ashlee Vance, *Data Analysts Are Mesmerized by the Power of Program R*, N.Y. Times, Jan. 7, 2009, at B6. The basic economic viability of the Internet, for example, rests in no small part on the accumulation, analysis, and distribution to advertisers of massive volumes of data regarding users’ interests. Traditional media is equally pervaded by publications devoted to the dissemination of commercial data. The daily stock report of the *Wall Street Journal* is only one obvious example among many. See generally Br. of Amicus Curiae Newsletter Publishers Ass’n, No. 98-678, *LAPD v. United Reporting Publ’g Corp.* 11-12 (collecting newsletters devoted to publishing reports of data in numerous fields, such as *Megawatt Daily*, *Inside Mortgage Finance*, and *Random Lengths*

(lumber prices)). The court of appeals' holding in this case strips all that truthful communication of any constitutional protection and provides a ready path for the government to interfere with the free flow of information in the knowledge-based economy of the twenty-first century any time it disagrees with the choices made by the consumers of information.

The First Circuit's judgment upholding New Hampshire's legislative effort to muzzle that speech warrants review for three reasons. First, the ruling is in irreconcilable conflict with this Court's First Amendment precedent. Second, the case directly implicates an important conflict in the circuits concerning the constitutionality of governmental efforts to regulate speech about factual information that has important value for social and commercial communication and, in particular, the appropriate standard of judicial scrutiny for such legislation. Third, the daily impact of this legislation on ongoing speech activities, as well as the proliferation of similarly speech-restricting statutes in other jurisdictions, necessitates this Court's prompt review of the statute's constitutionality. Two other states have already adopted similar statutes, and parallel measures have been introduced in roughly half the states. Indeed, the First Circuit itself recognized that the case "raises important constitutional challenges that lie at the intersection of free speech and cyberspace." Pet. App. 3.

Certiorari accordingly should be granted.

I. The First Circuit's Holding That Legislation Proscribing The Transfer Of Factual Information Merits Little, If Any, First Amendment Protection Conflicts With This Court's And Other Circuits' Precedent.

A. The Dissemination Of Truthful Factual Information Is Protected Speech.

The court of appeals' holding that the publication of truthful factual information falls completely "outside" the protection of the First Amendment (Pet. App. 22) warrants review because it defies this Court's precedent and because of the practical impact such a rule has on the free flow of information.

1. The First Circuit's conclusion that the truthful factual information at issue here lacks First Amendment protection because of its commercial or medical context flies in the face of settled free speech principles. A uniform line of precedent makes clear that, however beneficial or utilitarian the government might perceive a restraint in the free flow of information, the First Amendment trumps that judgment and debars government officials from using the suppression of communication as a tool of governance. *Virginia State Board of Pharmacy v. Virginia Consumer Counsel, Inc.*, 425 U.S. 748 (1976), held that a ban on the advertising of prescription drug prices violates the First Amendment. The Court expressly rejected the state's claim that the First Amendment is inapplicable because the advertising "merely reports a fact": "Purely factual matters of public interest may claim [First Amendment] protection," *id.* at 762, because it is "indispensable" to the "public interest" that there be a "free flow" of "information as to who is producing

and selling what product, for what reason, and at what price," *id.* at 765.

Other decisions have followed suit, underscoring that, in the commercial speech context in particular, the First Amendment protects the dissemination of truthful, factual marketplace information. *Edenfield v. Fane*, 507 U.S. 761 (1993), invalidated a ban on solicitation by certified public accountants because it "threaten[ed] societal interests in broad access to complete and accurate commercial information." *Id.* at 766. "[T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented." *Id.* at 767.

This Court has never deviated from that principle. Most recently, *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), held that the government may not prohibit pharmacists from advertising the availability of compounded drugs. "We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Id.* at 374. See, e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 564 (2001); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 489 (1996); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481-82 (1995). Cf. *Lowe v. SEC*, 474 U.S. 181, 210 (1985) ("[t]o the extent that the chart service contains factual information about past transactions and market trends, and the newsletters contain commentary on general market conditions, there can be no doubt about the protected character of the communications").

Majorities of this Court specifically have twice concluded that the transfer of pure data for commercial purposes is constitutionally protected. In *Dun & Bradstreet, Inc. v. Greenmoss Builders*, 472 U.S. 749 (1985), the Court applied First Amendment scrutiny to a libel suit regarding the private dissemination of factual reports on individuals' creditworthiness. A three-Justice plurality reasoned that the reports are constitutionally protected, although that protection is "reduced" because (in their view) it concerned "no public issue." *Id.* at 762 & n.8 (Powell, J., joined by Rehnquist and O'Connor, JJ.). Four other Justices would have applied full First Amendment scrutiny, reasoning that the "Court has consistently rejected the argument that speech is entitled to diminished First Amendment protection simply because it concerns economic matters or is in the economic interest of the speaker or the audience." *Id.* at 787 (Brennan, J., joined by Marshall, Blackmun, and Stevens, JJ.).

Subsequently, in *LAPD v. United Reporting Publishing Corp.*, 528 U.S. 32 (1999), the Court deemed premature a facial challenge to a statute providing that the government would not disclose arrest records – specifically, the names and addresses of arrestees – to be used for commercial purposes. The Ninth Circuit had held that such a use of arrest data constituted commercial speech. 146 F.3d. 1137 (9th Cir. 1999). In turn, a majority of the members of this Court agreed that a state prohibition on a private party distributing lawfully acquired arrest data for commercial purposes would be subject to First Amendment scrutiny. 528 U.S. at 44 (Ginsburg, J., joined by O'Connor, Souter, and

Breyer, JJ.) (such a statute "would indeed be a speech restriction if it . . . prohibited people from using that information to speak to or about arrestees"); *id.* at 46 (Stevens, J., joined by Kennedy, J.) (deeming it "indisputabl[e]" that if an entity lawfully "acquires the data, the First Amendment protects its right to communicate it to others").

The First Circuit's ruling in this case would be rejected on the reasoning of the majorities of this Court in both *Dun & Bradstreet* and *United Reporting*. But because neither of those cases confronted the issue in a opinion for the Court, the question remains unsettled as a matter of precedent. Certiorari should be granted here to remove that remaining uncertainty.

In all of this Court's relevant cases, the protected speech consisted of a piece of marketplace data – a price, a drug's existence, or the availability of a product – and in each the communication of that information was constitutionally protected speech. Given that precedent, the court of appeals' holding that truthful information about a doctor's prescribing practices falls completely outside the First Amendment's protection – diminished to the status of child pornography or fighting words – is indefensible. "We already have a code of 'fair information practices,' and it is the First Amendment, which generally bars the government from controlling the communication of information." Eugene Volokh, *Freedom of Speech and Information Privacy: The Troubling Implications of a Right to Stop People from Speaking About You*, 52 Stan. L. Rev. 1049, 1051 (2000).

2. Contrary to the ruling below, this Court has held that the categories of speech that are immune from constitutional scrutiny should be expanded, if at all, only grudgingly. The Court has withdrawn First Amendment protection only "in a few limited areas, which are 'of such slight social value as a step to truth that any benefit that may be derived from them is clearly outweighed by the social interest in order and morality.'" *R.A.V. v. St. Paul*, 505 U.S. 377, 382-83 (1992). It is only when the speech is affirmatively *harmful* – the imminent physical threat entailed in fighting words, and the horrific conduct that creates child pornography – that the absence of any countervailing value takes the speech outside the First Amendment realm. See *New York v. Ferber*, 458 U.S. 747, 759-64 (1982).

That rationale has no relevance here. Quite the opposite, it is precisely because the information has proven *value*, addresses "a matter of public concern," and is actively used and valued by decisionmakers (*IMS Health, Inc. v. Rowe*, 532 F. Supp. 2d 153, 166 n.12 (D. Me. 2007)) that the State wants to squelch it. New Hampshire's own asserted interest in enacting the PIL is that this truthful information has a direct relationship to the sale of brand-name drugs, which is the subject of a significant ongoing public debate.

Prescription history information is widely used to study the delivery of medical care and the spread of an array of medical conditions – not only by drug companies, but also by "biotechnology firms, pharmaceutical distributors, government agencies, insurance companies, health care groups, researchers, consulting organizations, the financial community, manufacturers of generic drugs,

pharmacy benefit managers, and others.” Pet. App. 157 n.2. The data is used “to track patterns of disease and treatment, conduct research and clinical trials, implement best practices, and engage in economic analyses.” *Id.* Even the First Circuit acknowledged that “[t]hese massive collections of information have great utility for certain non-profit entities (e.g., educational institutions, public interest groups, and law enforcement agencies).” *Id.* 6.

3. The court of appeals’ refusal to accord First Amendment protection to factual data conflicts not only with this Court’s precedent, but also with the rulings of other circuits. In the Second Circuit, “[e]ven dry information, devoid of advocacy, political relevance, or artistic expression, has been accorded First Amendment protection.” *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446-47 (2d Cir. 2001).

The Tenth Circuit likewise has held that the First Amendment protects a phone company’s use of its own customer information (CPNI) in making marketing decisions. See *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232 (10th Cir. 1999). In that case, the court specifically rejected the government’s “argu[ment] that the FCC’s CPNI regulations do not violate or even infringe upon [the company’s] First Amendment rights because they only prohibit the use of CPNI to target customers and do not prevent [the company] from communicating with its customers or limit anything that it might say to them.” *Id.* at 1232. “Such laws are subject to First Amendment scrutiny because they affect both the speaker’s ability to communicate with his intended audience and the audience’s right to receive information.” *Id.*

The D.C. and Tenth Circuits too have held that the distribution of factual commercial information is subject to First Amendment protection. *Nat'l Cable Television Ass'n, Inc. v. FCC*, 555 F.3d 996, 1000 (D.C. Cir. 2009) (accepting that regulation of transfers of CPNI information from telephone companies to joint venture partners "is a regulation of commercial speech," and applying First Amendment scrutiny); *Trans Union LLC v. FTC*, 295 F.3d 42, 52 (D.C. Cir. 2002); *Trans Union Corp. v. FTC*, 245 F.3d 809, 818, *reh'g denied*, 267 F.3d 1138 (D.C. Cir. 2001); *Lanphere & Urbaniak v. Colorado*, 21 F.3d 1508, 1513 (10th Cir. 1994) (prohibition on distribution of records for commercial purposes triggers First Amendment scrutiny because the government "has drawn a regulatory line based on [the] speech use of [the] records"), *cert. denied*, 513 U.S. 1044 (1994).

4. Because petitioners' speech is constitutionally protected, the court of appeals erred in holding that New Hampshire's law could bypass the First Amendment because the statute ostensibly criminalizes the "conduct" of acquiring, assessing, and distributing information, rather than the speech itself. That holding cannot be reconciled with this Court's precedent and, indeed, opens the door to troublingly broad regulatory power to proscribe quintessential speech activities. This Court has repeatedly held that the First Amendment forbids both direct and indirect restraints on the physical activities that are necessary to the communication and sharing of information – the mechanics of speaking.

In *Lorillard, supra*, for example, the Court gave no quarter to the claim that a regulation on the "placement" of cigarette advertising merely regulated conduct, explaining that the First Amendment was triggered whenever regulation of conduct "would impose particularly onerous burdens on speech." 533 U.S. at 564. That decision simply echoed this Court's repeated holdings that legislation regulating or proscribing the actions necessary to engage in communication triggers First Amendment scrutiny. *E.g., Minneapolis Star & Tribune Co. v. Minnesota Comm'r of Revenue*, 460 U.S. 575, 577, 592-93 (1983) (First Amendment applies to "use tax" on the cost of paper and ink products consumed in the production of a publication).

The First Amendment implications of New Hampshire's PIL are even more stark. The only "conduct" that it regulates is the act of communicating and interchanging truthful factual information. The proscribed activities thus can no more be divorced from the speech itself than could a regulation forbidding the "conduct" of distributing newspapers, the "conduct" of pamphletting, the "conduct" of broadcasting, or the "conduct" of mailing letters. The conduct is the act of communication and thus is precisely what the First Amendment protects.

Beyond that, simply declaring that conduct is the target of regulation does not strip the government of its First Amendment obligations. Conduct regulations that burden speech are justified only "if the governmental interest is unrelated to the suppression of free expression." *United States v. O'Brien*, 391 U.S. 367, 377 (1968). New Hampshire's only asserted interest, however, is in regulating the

speech itself – preventing petitioners' distribution of truthful factual information to drug companies, and the companies' subsequent "detailing" discussions with doctors. After all, if conduct were the State's true target, then the statute would not contain the multiple exemptions that it does allowing the distribution of the identical information as long as it is unrelated to the speech disfavored by the State.

The First Circuit opined that petitioners supposedly treat prescription information as a "commodity," indistinguishable from "beef jerky." Pet. App. 23. That is not correct: the distinguishing feature of petitioners' reports is that they are individualized – *not* commoditized – assessments of physician prescribing history. But in any event, the First Circuit's rationale makes no constitutional sense. For countless speakers who are indisputably cloaked with First Amendment protection – ranging from newspaper publishers to the providers of credit information to Internet sellers of sexually explicit material – speech could be described as a "commodity." It would stand the First Amendment on its head to hold that the more a speaker speaks, the less the Constitution applies. The world-wide circulation of *The New York Times* or the Internet publication of census data have as much constitutional stature as any isolated utterance.

B. The Court Of Appeals' Holding That Prescription Patterns Are Purely Commercial Speech Warrants Review Because It Expands A Conflict In The Circuits.

The First Circuit ruled, in the alternative, that if the First Amendment protects petitioners' prescription history information, it is at best commercial speech, the prohibition of which is subject to only intermediate scrutiny. That erroneous holding stands at the intersection of inconsistent precedents from this Court that have spawned a circuit conflict of surpassing importance.

In both *Board of Trustees of State University of New York v. Fox*, 492 U.S. 469, 473-74 (1989), and *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 422 (1993), this Court held that the category of "commercial speech" receiving lessened First Amendment protection is limited to statements that propose a commercial transaction. In *Central Hudson Gas & Electric Corporation v. Public Service Commission*, 447 U.S. 557 (1980), however, this Court more broadly defined commercial speech as "expression related solely to the economic interests of the speaker and its audience," *id.* at 561. See also *In re R. M. J.*, 455 U.S. 191, 204 n.17 (1982).

The courts of appeals have struggled for years with those competing definitions, producing a circuit conflict that the decision here expands. The First Circuit in this case acknowledged the narrow definition of "commercial speech" articulated in *Fox*, *supra*, but "reject[ed]" it on the basis of its own circuit precedent. Pet. App. 27-28 (citing *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 309 (1st Cir.

2005); *El Dia, Inc. v. P.R. Dep't of Consumer Affairs*, 413 F.3d 110 (1st Cir. 2005)). Three other circuits have adopted a similarly broad definition of commercial speech. In *SKF USA, Inc. v. U.S. Customs & Border Protection*, --- F.3d ---, 2009 WL 398263, at *12 (Fed. Cir. Feb. 12, 2009), the Federal Circuit approvingly invoked the decision in this case and concluded that the Supreme Court has "broadly defined 'commercial speech' as 'expression related solely to the economic interests of the speaker and its audience.'" The dissent, on the other hand, argued that a narrower definition applied because "*IMS* was incorrectly decided." *Id.* at *27 n.5 (Linn, J., dissenting). See also *Mason v. Florida Bar*, 208 F.3d 952, 955 (11th Cir. 2000); *Hoover v. Morales*, 164 F.3d 221, 225 (5th Cir. 1998).

By contrast, three other circuits apply the narrower definition adopted by this Court in *Fox* and *Discovery Network*. The Second, Fourth, Ninth and Tenth Circuits have held that "speech is not 'purely commercial' . . . if it does more than propose a commercial transaction"; when it does, "it is entitled to full First Amendment protection." *Mattel, Inc. v. MCA Records, Inc.*, 296 F.3d 894, 906 (9th Cir. 2002). Those courts recognize that "[u]se of the *Central Hudson* description as a definition of commercial speech might, for example, permit lessened First Amendment protection and increased governmental regulation for most financial journalism and much consumer journalism simply because they are economically motivated, a notion entirely without support in the case law." *CFTC v. Vartuli*, 228 F.3d 94, 110 n.8 (2d Cir. 2000). See also *Hoffman v. Capital Cities/ABC, Inc.*, 255 F.3d 1180, 1185 (9th

Cir. 2001); *Adventure Commc'ns, Inc. v. Kentucky Registry of Election Fin.*, 191 F.3d 429, 440 (4th Cir. 1999).

The conflict in the circuits concerning the proper definition of "commercial speech" thus is widespread and entrenched, and accordingly capable of resolution only by this Court's intervention. This case, moreover, directly implicates that conflict and squarely frames the question for this Court's decision. The communication prohibited by the PIL – petitioners' acquisition, analysis, and publication of prescription history data – does not propose a commercial transaction. Indeed, the PIL applies whether or not petitioners sell the information or instead give it away.

The subsequent "detailing" discussions between pharmaceutical companies and doctors likewise go far beyond proposing a commercial sale. As even the court of appeals acknowledged, detailers "focus on the weakness of the physician's erstwhile drug of choice as opposed to the clinical virtues of the detailed drug." Pet. App. 32.

This case highlights the social benefit of expression driven by the speaker's commercial interests, and thus would not only allow the Court to resolve the conflict in its own precedent and in the circuits, but would also provide it with the opportunity to revisit whether commercial speech should remain subject to lessened First Amendment protection. Petitioners' ability to publish profitably and free from government restraint generates tremendous social benefits. Detailing discussions produce an exchange of valuable, truthful information between doctors and pharmaceutical

companies about the medical benefits of particular drugs. Trial testimony in this case thus established that detailers regularly provide doctors with new and valuable information on important health topics, such as changes to "best practice" guidelines for treating illnesses. E.g., Trial Tr. 1-30-07, at 27-28, 31 (Wharton); *id.* at 20-21 (Cole). Furthermore, the process of detailing is a two-way street in which drug companies receive information from doctors regarding the efficacy of various treatments. *Id.* at 21 (Dr. Cole: "I'm being asked my opinion more than told my opinion"). Commercial sales also allow petitioners to provide prescription history information at little or no cost to governmental and non-profit organizations for their use in ongoing public health work. In depriving petitioners of any commercial benefit from their activities, the government will necessarily extinguish this vital social benefit of petitioners' speech.

II. The First Circuit's Holding That The PIL Survives First Amendment Scrutiny Was Wrong And The Implications Of Its Erroneous Holding Merit This Court's Intervention.

A. The Court Of Appeals' Holding That The Government Has A Substantial Interest In Inhibiting Truthful Communication Between Drug Companies And Doctors About The Merits Of Prescription Drugs Should Be Reversed.

The First Circuit's ruling strays so far from accepted First Amendment principles as to merit this Court's review to correct its enduring impact on

speech within that circuit's jurisdiction, and to resolve the circuit conflict it has spawned.

1. The First Circuit's rationale for upholding the law banning truthful factual speech of value to its audience was the State's determination to "level the playing field" for information about drugs by curtailing the amount of information detailers have, thereby purportedly "improv[ing] the quality of interactions between detailers and physicians." Pet. App. 12, 25-26.

In so holding, the court of appeals has given precedential sanction to the paternalistic goal of protecting doctors from truthful speech about the merits of brand-name drugs. New Hampshire is, quite literally, attempting to make it more difficult for drug companies and physicians to have an intelligent conversation. This Court has specifically rejected the "assumption that doctors would prescribe unnecessary medications" on the basis of drug advertising, because it "amounts to a fear that people would make bad decisions if given truthful information." *Western States*, 535 U.S. at 359.

The district court correctly recognized that, if the government has no cognizable interest in prohibiting professionals such as accountants from soliciting lay persons (*Edenfield v. Fane*, *supra*), then it manifestly has no such interest in the context of physician/pharmaceutical company discussions. "Health care providers are highly trained professionals who are committed to working in the public interest. They certainly are more able than the general public to evaluate truthful pharmaceutical marketing messages." Pet. App. 193. That is all the more true given that physicians can –

and regularly do – simply decline to meet with a drug company representative. Doctors can also designate their prescription history off limits for use by pharmaceutical sales representatives. *See supra* at 2-3. Thus, in practice, New Hampshire's law bars *only* truthful communications between drug companies and knowledgeable and willing doctors desirous of the information.

Likewise, New Hampshire's avowed desire to "level the playing field" to balance out drug companies' financial wherewithal (Pet. App. 25) directly parallels the premise repeatedly rejected by this Court that the government may limit individual expenditures in political campaigns. Under the First Amendment, the government may not inhibit speech just because it considers its influence to be economically outsized. *McConnell v. Fed. Election Comm'n*, 540 U.S. 93, 217-18 (2003); *Fed. Election Comm'n v. Massachusetts Citizens for Life, Inc.*, 479 U.S. 238, 263 (1986); *Buckley v. Valeo*, 424 U.S. 1, 39-51 (1976).

Compounding the court of appeals' error was its ratification of the statutory scheme's viewpoint discrimination. New Hampshire seeks to inhibit communication advocating the use of prescription drugs. At the same time, it permits insurers to use the identical information to promote the use of generic equivalents to those same drugs. *See* Trial Tr. 1-31-07, at 37-38 (Solbelson). And the State has adopted its own "counter detailing" program to use prescription history data to discourage brand-name drug use. *See supra* at 3-4. If the First Amendment means anything it means that the government

cannot outlaw the one side in a debate that it disfavors.

2. The court of appeals relied only on *Posadas de P.R. Associates v. Tourism Co.*, 478 U.S. 328 (1986), to vindicate New Hampshire's paternalistic agenda. See Pet. App. 40. But that makes review all the more appropriate. This Court has already cast substantial doubt on *Posadas* because its "precedent both preceding and following *Posadas* ha[s] applied the *Central Hudson* test more strictly." *Greater New Orleans Broadcasting Ass'n v. United States*, 527 U.S. 173, 182 (1999). Thus, in 44 *Liquormart, supra*, the Court reversed the First Circuit's holding that the state made a "reasonable choice" in prohibiting certain truthful alcohol advertising. A four-Justice plurality concluded that "*Posadas* clearly erred in concluding that it was 'up to the legislature' to choose suppression over a less speech-restrictive policy." 517 U.S. at 509 (Stevens, J., joined by Kennedy, Thomas, and Ginsburg, JJ.). Other members of the Court read *Posadas* narrowly, but declined to formally overrule it, because the facts of that case did not "require[] adoption of a new analysis for the evaluation of commercial speech regulation." *Id.* at 532 (O'Connor, J., joined by Rehnquist, C.J., and Souter and Breyer, JJ.).

By continuing to breathe life into *Posadas*, the court of appeals put its law at odds with that of other circuits, which have held that *Posadas* has been abrogated in relevant part. *Artichoke Joe's California Grand Casino v. Norton*, 353 F.3d 712, 737 n.20 (9th Cir. 2003) (the Supreme Court has "disavowed *Posadas*' First Amendment holding"); *Pearson v. Shalala*, 164 F.3d 650, 568 (D.C. Cir.

1999) ("the Supreme Court [has] expressly disapproved of that aspect of *Posadas*"). Only this Court can finally inter *Posadas* and bring uniformity to First Amendment law.

3. Review is also warranted to reverse the First Circuit's holding (Pet. App. 16) that petitioners' lack "standing" to argue that New Hampshire cannot assert an interest in limiting detailing because petitioners do not themselves engage in such discussions with doctors. There is in fact no dispute that petitioners have standing to challenge the constitutionality of the PIL, and the First Circuit itself adjudicated petitioners' suit. Petitioners have suffered an injury that would be redressed by a ruling in their favor: the PIL not only directly restricts petitioners' conduct, it also injures them by inhibiting their ability to acquire prescription history information from third parties. See generally *Summers v. Earth Island Inst.*, No. 07-463, slip op. at 4 (Mar. 3, 2008).

Nothing in law or logic supports the First Circuit's bizarre conclusion that, because New Hampshire's *defense* of the PIL rests on its desire to regulate the conduct of third parties, petitioners are precluded from explaining why the statute does not in fact advance a cognizable state interest. Petitioners have third-party standing to assert the claims of detailers. *U.S. Dep't of Labor v. Triplett*, 494 U.S. 715, 720 (1990). But in any event, principles of standing are not implicated when petitioners argue that the PIL cannot constitutionally be applied to *them* because it is not justified by an interest that is permissible under the First Amendment. Once the court has the power to

adjudicate petitioners' suit, it is not required to put on blinders to the merits of that claim. Thus, in *Western States, supra*, a pharmacy seeking to advertise compounded drugs filed suit, and the government defended the challenged regulation based on the claim that the advertising would distort communication between third parties – consumers and their doctors. This Court never doubted that the plaintiff pharmacy could dispute the government's assertion that it had a substantial interest in ensuring the accuracy of those third-party discussions.

The First Circuit's contrary holding produces an absurd jurisprudence that the framers of Article III could not have imagined. The court of appeals illogically invoked New Hampshire's interest in limiting brand-name drug sales while completely ignoring whether that interest was, in fact, legitimate. Pet. App. 16-17 ("We think it important to note, however, that this restriction on *jus tertii* rights does not prevent consideration of New Hampshire's interest in combating detailing."). Though the First Circuit left open the possibility that a drug advertiser could someday challenge the PIL (Pet. App. 46 n.10), that is a hollow hope, as the court of appeals held not only that the statute withstands constitutional scrutiny but also that the statute does *not* directly regulate drug companies and detailers (*id.* 13), which therefore face significant obstacles in establishing their own standing to bring suit.

B. The Court Of Appeals' Deference To The State Legislature And Refusal To Defer To The Findings Of The District Court Merit This Court's Review.

This Court has repeatedly held that "a government body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770-71. That burden is "not satisfied by mere speculation and conjecture" (*id.* at 770), nor by "anecdotal evidence and educated guesses" (*Rubin v. Coors Brewing Co.*, 514 U.S. 476, 490 (1995)).

In this case, the First Circuit concluded that the PIL sufficiently advances New Hampshire's interest in reducing prescription drug costs, notwithstanding that "there was no direct evidence on that point." Pet. App. 33. Concluding that "this is more a matter of policy than of prediction" (*id.* 35), the First Circuit held that it was obliged to "defer to the New Hampshire legislature" (*id.* 37). Although the district court had found to the contrary that the PIL would not advance the State's interest (*id.* 190), the First Circuit refused to defer to its findings, instead applying *de novo* review (*id.* 12).

The First Circuit's holding that New Hampshire need not justify the PIL through an adequate evidentiary record conflicts not only with this Court's precedents (*see supra*) but also with rulings of other circuits. *E.g.*, *Cal-Almond, Inc. v. United States Dep't of Ag.*, 14 F.3d 429, 437 (9th Cir. 1993) ("we may not simply defer to legislative and executive judgment," but "must determine ourselves whether the program directly advances USDA's asserted interests");

Adolph Coors Co. v. Brady, 944 F.2d 1543, 1551 (10th Cir. 1991) ("Requiring the government to affirmatively demonstrate a nexus between its legislative means and ends may appear an undue judicial intrusion on the legislative function [But] we cannot simply assume that particular means will accomplish certain ends because the legislature presumed they would and enacted them into law.").

There also is no support for the conclusion that New Hampshire was exempt from providing the evidentiary foundation required by the Constitution merely because it was the first state to adopt a statute similar to the PIL. The First Amendment has no "one free bite" exception to the obligation to establish that a speech restriction is tailored to directly advance a sufficient governmental interest. If anything, the district court correctly recognized that this is a particularly inappropriate context in which to defer to a legislative judgment. Not only did the New Hampshire legislature lack relevant "expertise" but it "acted quickly after the bill was introduced, received hearing testimony by numerous individuals who had yet to review proposed amendments, made no express findings either on the record or incorporated into the statute, failed to discuss alternative measures that would not restrict speech, and cited no evidence as to how effective the restriction might prove to be." Pet. App. 183 n.12.

Review is equally warranted of the First Circuit's refusal to defer to the findings of the district court. The court of appeals held that, because the case arose in the context of the First Amendment, it was required by *Bose Corp. v. Consumers Union of United*

States, Inc., 466 U.S. 485, 514 (1984), to engage in *de novo* review. Pet. App. 12. That ruling directly implicates an acknowledged, long-simmering conflict in the circuits. See *Don's Porta Signs, Inc. v. City of Clearwater*, 485 U.S. 981, 981 (1988) (White, J., dissenting from the denial of certiorari). Like the First Circuit, four other circuits apply *de novo* review on the basis of *Bose*.¹ By contrast, three other circuits hold that *de novo* appellate review applies only when they review rulings *rejecting* First Amendment claims.²

This case is an ideal vehicle to resolve this recurring conflict because the First Circuit's departure from the deference generally applicable to district court findings directly affected its holding that the PIL significantly advances an important governmental interest. The First Circuit rested its decision heavily on the State's assertion that detailing drives up health care costs by causing doctors to choose expensive brand-name drugs over less expensive generic equivalents. See Pet. App. 6-7 ("detailing is employed where a manufacturer seeks to encourage prescription of a patented brand-name drug as against generic drugs, or as against a

¹ See *United States v. Friday*, 525 F.3d 938 (10th Cir. 2008), *cert. denied*, 2009 WL 425168 (U.S. Feb. 23, 2009) (No. 08-6651); *Don's Porta Signs, Inc. v. City of Clearwater*, 829 F.2d 1051, 1053 n.9 (11th Cir. 1987); *Moore v. Morales*, 63 F.3d 358, 361 (5th Cir. 1995), *cert. denied*, 516 U.S. 1115 (1996).

² See *Multimedia Publ'g Co. v. Greenville-Spartanburg Airport Dist.*, 991 F.2d 154, 160 (4th Cir. 1993); *Daily Herald Co. v. Munro*, 838 F.2d 380, 383 (9th Cir. 1988); *Planned Parenthood Ass'n Chicago Area v. Chicago Transit Auth.*, 767 F.2d 1225, 1229 (7th Cir. 1985).

competitor's patented brand-name drug, or as a means of maintaining a physician's brand loyalty after its patent on a brand-name drug has expired"). By contrast, the district court specifically found that the PIL would not substantially reduce expenditures on brand-name drugs because "pharmaceutical companies generally *stop* detailing branded drugs when bioequivalent generic drugs become available." Pet. App. 191 n.15 (emphasis added). That conclusion is sound: the marginal profit on brand-name drug sales in that context is small, because states and insurers often mandate the use of available bioequivalent drugs. Thus, "the use of prescriber-identifiable data will not affect a prescriber's choice between a brand-name drug and a bioequivalent generic alternative." *Id.*

Detailing is instead principally directed at a doctor's choice between patent-protected drugs, or between a patent-protected drug and a non-bioequivalent generic alternative. The court of appeals did not contend that the PIL's broad restriction on speech could be justified merely because it reduced those limited effects on brand-name drug use. Other circuits would have deferred to the district court's factual finding and concluded on that basis that the PIL does not sufficiently advance New Hampshire's interest in reducing drug costs.

C. Certiorari Is Warranted To Review The Court Of Appeals' Holding That The PIL Is Valid Notwithstanding That The Statute Is Grossly Over- And Under-Inclusive.

In assessing whether a regulation of speech is sufficiently tailored to advance the government's asserted interests (*see supra* at 30 (citing *Edenfield v. Fane, supra*)), this Court's precedent consistently holds that the government may not adopt a prohibition that includes numerous exceptions which render it illogical or substantially ineffective. *Greater New Orleans, supra*, invalidated a prohibition on certain casino advertising, reasoning that "[t]he operation of [the statute] and its attendant regulatory regime is so pierced by exemptions and inconsistencies that the Government cannot hope to exonerate it." 527 U.S. at 190. In support, the Court cited *Rubin, supra*, which invalidated a ban on disclosing alcohol content on containers while permitting the disclosure of the same information in ordinary advertising. 514 U.S. at 488.

The Third Circuit applied those principles in *Pitt News v. Pappert*, 379 F.3d 96 (3d Cir. 2004) (Alito, J.). There, the government barred alcohol advertising in school-affiliated publications, but not other media. The Third Circuit held that the statute violated the First Amendment because it was "both severely over- and under-inclusive." *Id.* at 108. The law prohibited such advertising notwithstanding that most of the university population "is over the legal drinking age," and thereby "prevented the communication to adults of truthful information about products that adults could lawfully purchase and use." *Id.* Further, the

statute applied "to advertising in a very narrow sector of the media (*i.e.*, media associated with educational institutions), and the Commonwealth has not pointed to any evidence that eliminating ads in this narrow sector will do any good." *Id.* at 107.

In this case, the First Circuit held that there was a sufficient "fit" between the PIL and the State's asserted interests because no equally effective alternative existed that would restrict less speech. Pet. App. 41. That ruling cannot be reconciled with this Court's precedents because the First Circuit afforded no weight to the fact that the PIL is simultaneously under- and over-inclusive in the speech it restricts, and thus cannot possibly achieve the State's goals.

The PIL is grossly under-inclusive because, as construed by the First Circuit, it permits most New Hampshire prescription history data to be used in detailing. The statute allows that use whenever the data originates with "routine" transfers from New Hampshire pharmacies to the out-of-state data centers of pharmacy chains and insurers. Pet. App. 50. Because it is uncontested that "most prescriber-identifiable data leaves New Hampshire in this permissible manner" (*id.* 145 (separate opinion of Lipez, J.)), the First Circuit candidly admitted that the statute "may not accomplish very much" (*id.* 50 (majority opinion)) and will only produce "the closing of one aspect of the New Hampshire market" (*id.* 49). But it nonetheless held that the First Amendment permits New Hampshire to adopt the PIL as a "prophylactic" measure to protect against later non-routine distribution of the same information. *Id.* The statute thus directly bans some speech, and

chills much more through the threat of criminal prosecution, without significantly advancing the State's interests.

The PIL is equally over-inclusive because it prohibits detailing that does not implicate, or actually furthers, the State's interests. The statute is not limited to restricting those instances of detailing that cause doctors to make inappropriate prescribing decisions. To the contrary, the statute equally applies when the detailing identifies a *less expensive* alternative medication and when it conveys valuable information about drug treatments that improve public health, which is itself a significant state interest. A further significant proportion of detailing inhibited by the PIL involves competition between patent-protected brands that frequently has no effect on drug costs. *See supra* at 33. The First Circuit dismissed that fact as merely "not the state's primary concern" (Pet. App. 30 n.7), completely failing to recognize the statute's dramatic overbreadth. The PIL also prohibits *generic* manufacturers from electing to use prescription history information to market their less-expensive products to doctors. *See* Trial Tr. 1-29-07 at 9-10 (Sadek). In all those many instances, the statute inhibits speech without furthering – and often while undermining – New Hampshire's own claimed interests.

The First Circuit was also wrong to conclude that the PIL was valid because, in its view, petitioners could not identify "an alternative to the Prescription Information Law that promises to achieve the goals of the law without restricting speech." Pet. App. 41. In fact, New Hampshire (like other states) has adopted a "counter detailing" program designed to

achieve its goals by persuading doctors to prescribe fewer brand-name drugs. N.H. Rev. Stat. § 126-A:5, XVII. Other states have furthered cost containment through an array of other measures that do not restrict speech, many of which New Hampshire has not adopted.³

³ See, e.g., D.C. Code § 48-831.04 (2006) (requiring use of aggregate purchasing to negotiate lower prices of prescriber drugs); Fla. Stat. Ann. § 465.025 (2006) (requiring pharmacists to substitute generic drugs for bioequivalent brand-name drugs); N.H. Rev. Stat. Ann. § 318:47-d (2003) (authorizing pharmacists to substitute bioequivalent generic drugs); Me. Rev. Stat. Ann. tit. 22, § 2697 (2006) (prohibiting profiteering in prescription drugs); Me. Rev. Stat. Ann. tit. 22, § 2700-A (2006) (providing for consumer education about prescription drugs); Minn. Stat. § 151.461 (1994) (prohibiting gifts from drug manufacturers to health care practitioners); Vt. Stat. Ann. tit. 33, § 2005a (2006) (requiring sales representatives to disclose prices to prescribers); W. Va. Code Ann. § 5-16C-9 (2006) (setting forth a variety of strategies to reduce unnecessary prescription drug costs).

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

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Supreme Court, U.S.
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In The OFFICE OF THE CLERK
Supreme Court of the United States

IMS HEALTH INCORPORATED and VERISPAN LLC,

Petitioners,

v.

KELLY M. AYOTTE, AS ATTORNEY GENERAL
OF THE STATE OF NEW HAMPSHIRE,

Respondent.

**On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the First Circuit**

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550 F.3d 42

United States Court of Appeals,
First Circuit.

IMS HEALTH INC. and Verispan, LLC,
Plaintiffs, Appellees,

v.

Kelly A. AYOTTE, New Hampshire Attorney Gen-
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Defendant, Appellant.

No. 07-1945.

Heard Jan. 9, 2008.

Decided Nov. 18, 2008.

Laura E.B. Lombardi, Assistant Attorney General, with whom Richard W. Head, Associate Attorney General, was on brief, for appellant.

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Bert W. Rein, Andrew M. Miller, Joshua S. Turner, Wiley Rein LLP, and John Kamp on brief for Coalition for Healthcare Communications, amicus curiae.

Stephen J. Judge, Wadleigh, Starr & Peters, Donald B. Ayer, Donald Earl Childress III, and Jones Day on brief for Wolters Kluwer Health, Inc., amicus curiae.

Before LIPEZ, SELYA, and SILER,* Circuit Judges.

SELYA, Circuit Judge.

The spiraling cost of brand-name prescription drugs is a matter of great concern to government at every level. New Hampshire has attempted to curb

* Of the Sixth Circuit, sitting by designation.

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this escalating problem by enacting innovative legislation. Certain affected companies have challenged New Hampshire's legislative response, and that challenge raises important constitutional questions that lie at the intersection of free speech and cyberspace. The tale follows.

Pharmaceutical sales representatives, known in industry argot as "detailers," earn their livelihood by promoting prescription drugs in one-on-one interactions with physicians. A valuable tool in this endeavor, available through the omnipresence of computerized technology, is knowledge of each individual physician's prescribing history. With that informational asset, detailers are able to target particular physicians and shape their sales pitches accordingly. Convinced that this detailing technique induces physicians to prescribe expensive brand-name drugs in place of equally effective but less costly generic drugs, New Hampshire enacted a law that among other things prohibited certain transfers of physicians' prescribing histories for use in detailing. See 2006 N.H. Laws § 328, *codified at* N.H.Rev.Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006) (the Prescription Information Law). A duo of data miners promptly challenged the law as invalid on various grounds. The district court found that it worked an unconstitutional abridgement of free speech and enjoined its enforcement. See *IMS Health Inc. v. Ayotte*, 490 F.Supp.2d 163, 183 (D.N.H.2007) (D.Ct.Op.). This appeal ensued.

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In the pages that follow, we explain why we are not persuaded that the regulated data transfers embody restrictions on protected speech. In our view, the portions of the law at issue here regulate conduct, not speech. Unlike stereotypical commercial speech, new information is not filtered into the marketplace with the possibility of stimulating better informed consumer choices (after all, physicians already know their own prescribing histories) and the societal benefits flowing from the prohibited transactions pale in comparison to the negative externalities produced. This unusual combination of features removes the challenged portions of the statute from the proscriptions of the First Amendment.

There is a second basis for our decision. Even if the Prescription Information Law amounts to a regulation of protected speech – a proposition with which we disagree – it passes constitutional muster. In combating this novel threat to the cost-effective delivery of health care, New Hampshire has acted with as much forethought and precision as the circumstances permit and the Constitution demands.

I. BACKGROUND

The raw facts are largely undisputed. Modern-day detailing begins when a prescription is filled.¹ At

¹ Our description of detailing owes much to the precise accounts provided by two district courts, including the court
(Continued on following page)

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that moment, the pharmacy stores in its computerized database a potpourri of information about the transaction, such as the name of the patient, the identity of the prescribing physician, the drug, its dosage, and the quantity dispensed. Due to the complex relationships that mark the delivery of health care products and services in the twenty-first century, this information quickly finds its way into other databases, including those of insurance carriers and pharmacy benefits managers.

The plaintiffs in this case, IMS Health Inc. and Verispan, LLC, are in the business of data mining. For present purposes, that means that they purchase data of the type and kind described above, aggregate the entries, group them by prescriber, and cross-reference each physician's prescribing history with physician-specific information available through the American Medical Association. The final product enumerates the prescriber's identity and speciality, the drug prescribed, and kindred information. The scope of the enterprise is mind-boggling: these two plaintiffs alone record, group, and organize several billion prescriptions each year. To protect patient privacy, prescribees' names are encrypted, effectively eliminating the ability to match particular prescriptions with particular patients.

below. See *IMS Health Corp. v. Rowe*, 532 F.Supp.2d 153, 157-65 (D.Me.2007); D. Ct. Op., 490 F.Supp.2d at 165-74.

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These massive collections of information have great utility for certain non-profit entities (e.g., educational institutions, public interest groups, and law enforcement agencies). New Hampshire's concern, however, is with a frankly commercial use: the exploitation of the mined data by pharmaceutical companies, whose detailers use it in marketing drugs to physicians.

At this point, the art of detailing warrants further elaboration. Detailing involves tailored one-on-one visits by pharmaceutical sales representatives with physicians and their staffs. This is time-consuming and expensive work, not suited to the marketing of lower-priced bioequivalent generic drugs (drugs that are pharmacologically indistinguishable from their brand-name counterparts save for potential differences in rates of absorption). The higher profit margins associated with brand-name drugs leaves the personal solicitation field open to brand-name drug manufacturers, who in the year 2000 spent roughly \$4,000,000,000 on detailing.²

Brand-name drug manufacturers engage in detailing in several situations. For instance, detailing is employed where a manufacturer seeks to encourage prescription of a patented brand-name drug as

² Because of the ready availability of reliable figures, the parties used the year 2000 as a benchmark year for illustrative purposes. It is clear from the anecdotal evidence that both the incidence of detailing and the gross amounts expended in its service have increased in the intervening years.

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against generic drugs, or as against a competitor's patented brand-name drug, or as a means of maintaining a physician's brand loyalty after its patent on a brand-name drug has expired.

If a physician's prescribing habits present an appropriate opportunity, the detailer attempts to gain access to the physician's office, usually by presenting herself as a helpful purveyor of pharmaceutical information and research. The detailer comes to the physician's office armed with handouts and offers to educate the physician and his staff about the latest pharmacological developments. In other words, detailers open doors by holding out the promise of a convenient and efficient means for receiving practice-related updates.

Withal, a physician's time is precious, and detailers must manage their way around physicians' natural reluctance to make time for promotional presentations. To this end, detailers typically distribute an array of small gifts to physicians and their staffs, host complimentary lunches, and pass out free drug samples. From time to time, a detailer will invite a physician to attend an all-expense-paid conference or to accept a lucrative speaking engagement.

Most of these freebies cut very little ice. The free samples, however, are highly prized. Their sheer volume is astounding: in the year 2000, an estimated \$1,000,000,000 in free drug samples flowed from detailers to physicians. That flood of free medications

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enables physicians to offer drugs free of charge to selected patients. Many physicians thus tolerate detailing visits in order to reap the harvest of samples that these visits bring.³

Once inside a physician's office, detailers are capable of mounting an impressively sophisticated and intense marketing pitch. The detailer works to establish an ongoing relationship with the physician and, in most cases, detailers' visits become a regular occurrence. For example, the average primary care physician interacts with no fewer than twenty-eight detailers each week and the average specialist interacts with fourteen.

Given the frequency of these exchanges, it is not surprising that prescriber-identifiable information can be an invaluable asset to the detailer. That information enables the detailer to zero in on physicians who regularly prescribe competitors' drugs, physicians who are prescribing large quantities of drugs for particular conditions, and "early adopters" (physicians with a demonstrated openness to prescribing drugs that have just come onto the market). The information also allows the detailer to tailor her promotional message in light of the physician's prescribing history.

³ Nevertheless, a significant number of physicians flatly refuse detailing visits, convinced that they are either unethical or a waste of time.

II. THE LEGISLATIVE RESPONSE

In time, the New Hampshire legislature moved to combat what it saw as a pernicious effect of detailing. On January 4, 2006, a bill, which would become the Prescription Information Law, was introduced in the House of Representatives. Hearings before the House and Senate followed. Those hearings made the goals of the proposed statute pellucid: the protection of privacy interests, the safeguarding of patient health, and cost containment. Testimony taken at the hearings indicated that the last of these was the bill's driver.

In due course, the proposed bill passed both chambers, was signed by the governor, and took effect on June 30, 2006. In relevant part it provides:

Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or

market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

N.H.Rev.Stat. Ann. § 318:47-f.

The statute further provides that nothing contained in this language should be read to prohibit the dispensing of prescription medications to a patient, the transmission of prescription information either between a prescriber and a pharmacy or between pharmacies, the transfer of prescription records evident to a pharmacy's change in ownership, the distribution of care management materials to a patient, or the like. *Id.* The statute makes explicit that nothing in the above-quoted language should be read to "prohibit the collection, use, transfer, or sale of patient and prescriber de-identified data by zip code, geographic region, or medical specialty for commercial purposes." *Id.* Last – but surely not least – it provides both criminal and civil penalties for violations. *Id.* §§ 318:55, 358-A:6.

III. THE LITIGATION

Within a month of the effective date of the Prescription Information Law, the plaintiffs initiated this constitutional challenge. They filed a civil action in the United States District Court for the District of New Hampshire, naming the Attorney General in her official capacity as the defendant and seeking

declaratory and injunctive relief. Their complaint alleged that the statutory ban on transfer and use of prescriber-identifiable information transgressed the Free Speech Clause of the First Amendment, was void for vagueness, and offended the Commerce Clause.

A period of expedited discovery and a four-day bench trial ensued. The district court took the matter under advisement and subsequently wrote a thoughtful rescript in which it concluded that the Prescription Information Law regulated speech, not conduct. D. Ct. Op., 490 F.Supp.2d at 174-75. Accordingly, it applied the conventional constitutional test for commercial speech, inquiring whether the law (i) supported a substantial government interest, (ii) directly advanced that interest, and (iii) was more extensive than necessary to serve that interest. *Id.* at 177 (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980)).

The district court found the governmental interests advanced in support of the law insufficient. *Id.* at 178-81 & n. 13. With specific reference to cost containment, the court maintained that the state had failed to prove that substituting non-bioequivalent generic drugs for brand-name drugs would be generally advantageous to patients' health. *Id.* at 180-81. The court also said that cost containment could not satisfy the third prong of the *Central Hudson* test because so many other regulatory options existed for curtailing detailing – none of which would involve

restrictions on speech. *See id.* at 181-83 (listing continuing medical education, gift bans, and possible revisions of the state's Medicaid program).

In the end, the court declared the relevant portions of the Prescription Information Law unconstitutional and enjoined its enforcement. *Id.* at 183. The court did not reach the plaintiffs' other constitutional challenges.

This timely appeal followed. The issues raised engender de novo review. *See Bose Corp. v. Consumers Union*, 466 U.S. 485, 514, 104 S.Ct. 1949, 80 L.Ed.2d 502 (1984); *Mandel v. Boston Phoenix, Inc.*, 456 F.3d 198, 209 (1st Cir.2006).

IV. STANDING

"Standing is a threshold issue in every federal case." *Berner v. Delahanty*, 129 F.3d 20, 23 (1st Cir.1997). It bears directly upon a court's power to adjudicate a dispute. *Id.* Consequently, we first address an issue of standing – an issue that touches upon the nature of the conduct that should serve as the focal point of our inquiry.

New Hampshire has sought to improve the quality of interactions between detailers and physicians by regulating upstream transactions of prescriber-identifiable information between data miners and those who would put that information to use in detailing. The state directs our attention to these prohibited upstream transactions, claiming that they

comprise the relevant conduct for present purposes. The plaintiffs demur, positing that the relevant conduct is composed of the downstream interactions between detailers and physicians because it is those interactions that the legislature intended to affect. The district court sided with the plaintiffs on this point. *See* D. Ct. Op., 490 F.Supp.2d at 175.

The record reveals that three sets of transactions are interwoven here. These include (i) the data miners' acquisition of prescriber-specific information from pharmacies and others; (ii) the data miners' sale of that information (now processed) to pharmaceutical companies for use in detailing (transfers for other purposes are exempted); and (iii) the use of that information by pharmaceutical company detailers to promote particular products to physicians. New Hampshire chose to regulate the first and second of these transactional subsets, not the third. Given this model, basic principles of standing jurisprudence help us to resolve this preliminary dispute.

"A party ordinarily has no standing to assert the First Amendment rights of third parties." *Wine & Spirits Retailers, Inc. v. Rhode Island* (*Wine & Spirits I*), 418 F.3d 36, 49 (1st Cir.2005); *accord Eulitt ex rel. Eulitt v. Me. Dep't of Educ.*, 386 F.3d 344, 351 (1st Cir.2004). No pharmaceutical company, detailer, or physician is a party in this case.⁴ It follows that

⁴ To be sure, some of the amici profess to represent such interests. But, absent special circumstances (not present here),

(Continued on following page)

unless they can come within some exception to the general *jus tertii* principle, the plaintiffs lack standing to assert the First Amendment rights of the participants in the targeted downstream (third-stage) interactions. In other words, they cannot assert the rights of detailers to use prescriber-identifiable information in communicating face-to-face with physicians, nor can they assert the rights of physicians to receive that information during such interactions. *Cf. U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232 (10th Cir.1999) (considering commercial speech rights where the plaintiff directly sought to use the information for its own marketing).

The plaintiffs convinced the district court that the exception laid down in *Craig v. Boren*, 429 U.S. 190, 194-95, 97 S.Ct. 451, 50 L.Ed.2d 397 (1976), allowed their assertion of third-party rights. *See D. Ct. Op.*, 490 F.Supp.2d at 175 n. 10 (citing *Craig* for the proposition that vendors may assert the rights of their customer base). We think that in so concluding the court lost sight of the narrowness of this *jus tertii* exception. *See Wine & Spirits I*, 418 F.3d at 49 (characterizing the exception as "isthmian" and refusing to allow franchisor to assert First Amendment rights of franchisees).

issues advanced exclusively by an amicus ought not to be considered on appeal. *See, e.g., United States v. Bongiorno*, 106 F.3d 1027, 1034 (1st Cir.1997); *United States v. Taylor*, 54 F.3d 967, 972 (1st Cir.1995); *Lane v. First Nat'l Bank*, 871 F.2d 166, 175 (1st Cir.1989).

The exception is rooted in practical considerations. Under it, a litigant will be permitted to raise a third party's rights only when three criteria are met: the third party has suffered a constitutional injury in fact, the litigant enjoys a close relationship with the third party, and an obstacle exists to the third party assertion of his or her own rights. *See Powers v. Ohio*, 499 U.S. 400, 410-11, 111 S.Ct. 1364, 113 L.Ed.2d 411 (1991) (citing *Craig*, 429 U.S. at 190, 97 S.Ct. 451).

The inapplicability of the exception is evident. There is no indication in the record that pharmaceutical companies, detailers, or physicians are somehow incapable of or inhibited from vindicating their own rights. In the absence of any such barrier, *Craig* does not pertain. *See Eulitt*, 386 F.3d at 352-53; *see also Singleton v. Wulff*, 428 U.S. 106, 110, 114-16, 96 S.Ct. 2868, 49 L.Ed.2d 826 (1976).

Of course, the Court has indicated some willingness to relax third-party standing in the First Amendment context. *See Kowalski v. Tesmer*, 543 U.S. 125, 130, 125 S.Ct. 564, 160 L.Ed.2d 519 (2004). But in practical terms, this relaxation evinces nothing more than a receptiveness to facial attacks on allegedly overbroad laws. *See Osediacz v. City of Cranston*, 414 F.3d 136, 140 (1st Cir.2005). Otherwise, hindrance – the existence of an obstacle to the vindication of one's own rights – remains a necessary prerequisite; and no court has exhibited a willingness to write the hindrance element out of the standing

test as a matter of general convenience.⁵ See *Wine & Spirits I*, 418 F.3d at 49; Richard H. Fallon, Jr., *As-Applied and Facial Challenges and Third Party Standing*, 113 Harv. L.Rev. 1321, 1359-64 (2000); see also *Osediacz*, 414 F.3d at 140 n. 2 (noting that "[e]ven this limited relaxation . . . is controversial"). Thus, the data miners must assert their own rights and explain how those rights are infringed by the operation of the Prescription Information Law.

As we proceed, we restrict our analysis to whether the data miners' activities – the acquisition, aggregation, and sale of prescriber-identifiable data – constitute speech or conduct and whether New Hampshire's legitimate governmental interests are sufficient to counterbalance any speech rights inherent therein. We think it important to note, however, that this restriction on *jus tertii* rights does not

⁵ The dissent seems to equate prudential standing rules with precatory guidelines. That is an incorrect assessment. Although the Court has said that prudential standing doctrine derives primarily from pragmatic concerns, that is a far cry from saying that standing rules can be ignored by a district court in the interests of expediency. See *Valley Forge Christian Coll. v. Americans United for Sep'n of Church and State, Inc.*, ("Merely to articulate these principles is to demonstrate their close relationship to the policies reflected in the Art. III requirement of actual or threatened injury amenable to judicial remedy."). For example, the prohibition against adjudicating generalized grievances is a prudential doctrine – but we can find no case in which that barrier has been lifted in the interest of pragmatism. Here, then, detouring around third-party standing rules requires a showing of hindrance. See *Kowalski*, 543 U.S. at 129-30, 125 S.Ct. 564.

prevent consideration of New Hampshire's interest in combating detailing. Standing rules are at bottom a limitation on a court's competence to adjudicate a dispute. See *Warth v. Seldin*, 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975). Conversely, consideration of a state's interest addresses the state's power to enact laws and is in no way denigrated by a lack of standing. After all, courts long have recognized that a law may be predicated on criteria broader than those presented by a particular case. See, e.g., *Crawford v. Marion Cty. Election Bd.*, ___ U.S. ___, 128 S.Ct. 1610, 1623, 170 L.Ed.2d 574 (2008); *Gonzales v. Raich*, 545 U.S. 1, 17, 125 S.Ct. 2195, 162 L.Ed.2d 1 (2005).

V. SPEECH OR CONDUCT?

The next issue requires a determination of whether or not the challenged portions of the Prescription Information Law regulate protected speech. The state offers a simplistic solution to this nuanced problem: it asseverates that the law falls under the exception to First Amendment coverage limned in *Bartnicki v. Vopper*, 532 U.S. 514, 121 S.Ct. 1753, 149 L.Ed.2d 787 (2001), so that it may prohibit the use of prescriber-identifiable information without further ado. See *id.* at 526-27, 121 S.Ct. 1753 (dictum).

Bartnicki does not take the state very far. The *Bartnicki* Court confronted a bizarre situation, in which an illegally intercepted wire communication fell fortuitously into the hands of an individual who

had neither played a role in its interception nor knew the interceptor. Given that the information bore upon a matter of public concern, the Court opined that Congress could not constitutionally prohibit the disclosure of that information by the innocent recipient. *Id.* at 534, 121 S.Ct. 1753. In so concluding, it introduced a distinction between "use" and "disclosure" of illegally intercepted communications: the First Amendment allowed absolute prohibition of the former but only allowed prohibition of the latter when the discloser had participated in the interception. *Id.* at 529, 121 S.Ct. 1753. It carefully distinguished the situation at hand from other situations in which valid laws prohibited the use of illegally intercepted wire communications. *See id.* at 527 n. 10, 121 S.Ct. 1753.

The state does not explain why *Bartnicki* should be understood to shed light on the instant case, and we believe that any comparison is inapt. The facts of the two cases are materially distinguishable, and the state's expansive reading of *Bartnicki* is insupportable on policy grounds. Were the state capable of forbidding every use of information regardless of the specific nature of either the use or the information, the state's power to control the flow of information would be nearly absolute. The First Amendment does not protect the rights of persons to give and receive information only to allow the wholesale prohibition of its use by government fiat. While various uses of transferred information can be barred or restricted for independent reasons (licensing agreements are a

prime example), they cannot be prohibited merely because they are "uses."

Rejecting the state's mechanistic reliance on *Bartnicki* is only the beginning, not the end. Although *Bartnicki* does not control, we nonetheless believe that what the state seeks to regulate here is conduct, not expression. This case poses the relatively narrow question of whether the Prescription Information Law constitutionally may bar these plaintiffs (data miners) from aggregating, manipulating, and transferring data for one particular purpose only. This brings vividly to mind Chief Justice Roberts's admonition that "it has never been deemed an abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc. (FAIR)*, 547 U.S. 47, 62, 126 S.Ct. 1297, 164 L.Ed.2d 156 (2006) (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502, 69 S.Ct. 684, 93 L.Ed. 834 (1949)).

We recognize, of course, that pure informational data can qualify for First Amendment protection. See *Univ'l City Studios, Inc. v. Corley*, 273 F.3d 429, 446-47 (2d Cir.2001) ("Even dry information, devoid of advocacy, political relevance, or artistic expression, has been accorded First Amendment protection."); see also *Va. Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976) (deeming ordered pairs of drug prices and products commercial speech). But that coin

has a flip side. As Justice Holmes famously observed, "the First Amendment while prohibiting legislation against free speech as such cannot have been, and obviously was not, intended to give immunity for every possible use of language." *Frohwerk v. United States*, 249 U.S. 204, 206, 39 S.Ct. 249, 63 L.Ed. 561 (1919).

The proof of this pudding is that entire categories of speech receive no protection at all from the First Amendment. Some have been explicitly recognized as lying outside the compass of the Free Speech Clause by virtue of longstanding tradition. See, e.g., *Chaplinsky v. New Hampshire*, 315 U.S. 568, 571-72, 62 S.Ct. 766, 86 L.Ed. 1031 (1942) (listing as examples "the lewd and obscene, the profane, the libelous, and the insulting or 'fighting' words"); see also *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002) (explaining that false or misleading commercial speech may be barred completely without constitutional concern).

There are other species of speech-related regulations that effectively lie beyond the reach of the First Amendment. These include agreements in restraint of trade, see, e.g., *Nat'l Soc'y of Prof. Eng'rs v. United States*, 435 U.S. 679, 697-98, 98 S.Ct. 1355, 55 L.Ed.2d 637 (1978); communications in furtherance of crimes, see, e.g., *Giboney*, 336 U.S. at 498, 69 S.Ct. 684; statements or actions creating hostile work environments, see, e.g., *O'Rourke v. City of Prov.*, 235 F.3d 713, 735 (1st Cir.2001); and promises of benefits made by an employer during a union election, see,

e.g., *NLRB v. Gissel Packing Co.*, 395 U.S. 575, 618-20, 89 S.Ct. 1918, 23 L.Ed.2d 547 (1969). The Supreme Court has recognized that these exceptions exist, see, e.g., *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 515, 92 S.Ct. 609, 30 L.Ed.2d 642 (1972); see also Richard H. Fallon, Jr., *Sexual Harassment, Content Neutrality, and the First Amendment Dog That Didn't Bark*, 1994 Sup.Ct. Rev. 1, 8, but for whatever reason, the Justices have never deemed it necessary to address why or how these content-based prohibitions manage to escape First Amendment scrutiny. Thus, these laws loom as tacit but unexplained exceptions to the suzerainty of the First Amendment. See *Wine & Spirits I*, 418 F.3d at 53.

Scholars have labored to formulate theories about why First Amendment immunity exists in such cases. See, e.g., Neil M. Richards, *Reconciling Data Privacy and the First Amendment*, 52 U.C.L.A. L.Rev. 1149, 1165-74 (2005); Frederick Schauer, *The Boundaries of the First Amendment: A Preliminary Exploration of Constitutional Salience*, 117 Harv. L.Rev. 1765, 1777-84 (2004). Despite these efforts, the matter remains a doctrinal mystery.

In our view, the most natural explanation for this phenomenon is that this complex of de facto exceptions derives from a felt sense that the underlying laws are inoffensive to the core values of the First Amendment – inoffensive because they principally regulate conduct and, to the extent that they regulate speech at all, that putative speech comprises items of

nugatory informational value. It is this unusual combination of features that distinguishes these laws and places them outside the ambit of the First Amendment. *Cf. Chaplinsky*, 315 U.S. at 572, 62 S.Ct. 766 (explaining inapplicability of First Amendment to fighting words because these words are "of such slight social value as a step to truth that any benefit that may be derived from them is clearly outweighed by the social interest in order and morality").

We believe that the transfers of prescriber-identifiable information regulated by the Prescription Information Law (transfers that otherwise would flow from pharmacies to data miners to detailers for the purpose of promoting the dispensation of expensive brand-name drugs) fit within this integument. The challenged portions of the statute principally regulate conduct, and to the extent that the challenged portions impinge at all upon speech, that speech is of scant societal value.

We say that the challenged elements of the Prescription Information Law principally regulate conduct because those provisions serve only to restrict the ability of data miners to aggregate, compile, and transfer information destined for narrowly defined commercial ends. In our view, this is a restriction on the conduct, not the speech, of the data miners. *Cf. Wine & Spirits I*, 418 F.3d at 49 (viewing "provision of advertising services, including designing advertisements, arranging for their placement in various media, and licensing the common use of trade names" as conduct rather than speech). In other

words, this is a situation in which information itself has become a commodity. The plaintiffs, who are in the business of harvesting, refining, and selling this commodity, ask us in essence to rule that because their product is information instead of, say, beef jerky, any regulation constitutes a restriction of speech. We think that such an interpretation stretches the fabric of the First Amendment beyond any rational measure.

The plaintiffs advance two related theories as to why their information processing constitutes speech. First, they analogize their situation to that of a newspaper, noting that they, like a newspaper, collect information of public concern, analyze it, and distribute it for a fee. Second, they liken this case to those in which the Supreme Court has struck down commercial speech restrictions on the ground that the speech contributes to the efficiency of the marketplace. The response to both of these arguments is rooted in the conduct/speech distinction: While the plaintiffs lip-synch the mantra of promoting the free flow of information, the lyrics do not fit the tune.⁶ The Prescription Information Law simply does not prevent any information-generating activities. The plaintiffs may

⁶ Characterizing the Prescription Information Law as a paternalistic ban on the influx of information into the marketplace misses the point. Detailers do not routinely disclose a physician's prescribing history to that physician. Indeed, many physicians who interact with detailers never discover that the detailers possess such information.

still gather and analyze this information; and may publish, transfer, and sell this information to whom-ever they choose *so long as that person does not use the information for detailing*. Like in *FAIR*, 547 U.S. at 62, 126 S.Ct. 1297, the restriction here is on the conduct (detailing) not on the information with which the conduct is carried out.

The plaintiffs' true complaint, of course, is that in banning this use of their data, we risk drying up the market for their services. To that concern we repeat: "the First amendment does not safeguard against changes in commercial regulation that render previously profitable information valueless." *Wine & Spirits I*, 418 F.3d at 48. In that case, we offered an example of the closure of a tax loophole rendering tax-shelter information worthless. *See id.* It is the same here: the seller of information can not be heard to complain that its speech is infringed by a law making the most profitable use of that information illegal. *See id.* ("The First Amendment's core concern is with the free transmission of a message or idea from speaker to listener, not with the speaker's ability to turn a profit.").

Although speech, protected or not, is implicated by the Prescription Information Law, it consists primarily of communications between detailers and doctors – but no detailer or doctor is a plaintiff here. Therefore, an adjudication of that aspect of the law must await a proper plaintiff.

We add, moreover, that the fact that this information can be freely transferred to anyone for non-detailing purposes renders this case a world apart from statutes that have been struck down in the interest of "provid[ing] a forum where ideas and information flourish." *Thompson*, 535 U.S. at 367, 122 S.Ct. 1497 (quoting *Edenfield v. Fane*, 507 U.S. 761, 767, 113 S.Ct. 1792, 123 L.Ed.2d 543 (1993)); see also 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 516, 116 S.Ct. 1495, 134 L.Ed.2d 711 (1996) (striking down statute prohibiting advertisement of liquor prices); *Edenfield*, 507 U.S. at 777, 113 S.Ct. 1792 (striking down statute prohibiting in-person solicitation by accountants); *Va. Bd. of Pharm.*, 425 U.S. at 771-73, 96 S.Ct. 1817 (striking down statute prohibiting advertisement of price information for drugs).

Pharmaceutical detailing has pushed the art of marketing into uncharted waters. In the service of maximizing drug sales, detailers use prescribing histories as a means of targeting potential customers more precisely and as a tool for tipping the balance of bargaining power in their favor. As such, detailing affects physician behavior and increases the likelihood that physicians will prescribe the detailers' (more expensive) drugs. The New Hampshire legislature found this advantage in bargaining power invidious (chiefly because of its inflationary impact on drug prices) and determined that it compromised the integrity of physician decisionmaking. Consequently, the legislature sought to level the playing field not by eliminating speech but, rather, by eliminating the

detailers' ability to use a particular informational asset – prescribing histories – in a particular way.

To be sure, certain information exchanges are foreclosed by the Prescription Information Law. They are not, however, the sorts of exchanges valued by the Supreme Court's First Amendment jurisprudence but, rather, are exchanges undertaken to increase one party's bargaining power in negotiations. We believe that in moving to combat the novel problems presented by detailing in the information age, New Hampshire has adopted a form of conduct-focused economic regulation that does not come within the First Amendment's scope.

Accordingly, we hold that the challenged portions of the Prescription Information Law fall outside the compass of the First Amendment. They thus engender rational basis review as a species of economic regulation. See, e.g., *Nat'l Amusements, Inc. v. Town of Dedham*, 43 F.3d 731, 736 (1st Cir.1995). The plaintiffs concede that the challenged portions of the law survive that modest level of scrutiny. The challenge under the Free Speech Clause must, therefore, fail.

VI. FIRST AMENDMENT SCRUTINY

Although we could end our odyssey here, there is another path open to us that leads to the same distinction. Even if the Prescription Information Law is treated as a restriction on protected speech, it is

nonetheless constitutional. This, then, constitutes an alternative ground for our decision.

Assuming, *arguendo*, that the acquisition, manipulation, and sale of prescriber-identifiable data comes within the compass of the First Amendment, the Prescription Information Law would have to survive intermediate scrutiny as a regulation of commercial speech. *See Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 623, 115 S.Ct. 2371, 132 L.Ed.2d 541 (1995). As we explained above, *see supra* Part IV, the plaintiffs lack standing to assert the rights of the pharmaceutical companies, the detailers, or the physicians. Their challenge must therefore rise or fall based on the curtailment of their own rights (rights emanating from the upstream transactions to which they are privy).

If speech at all, these transactions are commercial speech; that is, they at most embody "expression related solely to the economic interest of the speaker and its audience." *Cent. Hudson*, 447 U.S. at 561, 100 S.Ct. 2343. While the plaintiffs argue for a narrower definition of commercial speech limited to activities "propos[ing] a commercial transaction," *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473-74, 109 S.Ct. 3028, 106 L.Ed.2d 388 (1989), the case law is inhospitable to this argument. *See, e.g., Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 309 (1st Cir.2005); *El Día, Inc. v. P.R. Dep't of Consumer Affairs*, 413 F.3d 110, 115 (1st Cir.2005). We therefore reject it and conclude instead that the Prescription Information Law, if regarded as a restriction on protected speech,

must be analyzed under the rubric of commercial speech.

That conclusion brings front and center the familiar *Central Hudson* test. Under *Central Hudson* – so long as the speech in question concerns an otherwise lawful activity and is not misleading – statutory regulation of that speech is constitutionally permissible only if the statute is enacted in the service of a substantial governmental interest, directly advances that interest, and restricts speech no more than is necessary to further that interest. See *Cent. Hudson*, 447 U.S. at 556, 100 S.Ct. 2343; *Wine & Spirits Retailers, Inc. v. Rhode Island (Wine & Spirits II)*, 481 F.3d 1, 8 (1st Cir.2007). In administering this test, we must remain mindful that the party seeking to sustain a restriction on commercial speech bears the burden of justifying that restriction. *Thompson*, 535 U.S. at 373, 122 S.Ct. 1497; *Edenfield*, 507 U.S. at 770, 113 S.Ct. 1792.

On behalf of the Prescription Information Law, New Hampshire cites three governmental interests: maintaining patient and prescriber privacy, protecting citizens' health from the adverse effects of skewed prescribing practices, and cost containment. For simplicity's sake, we restrict our analysis to the third of these interests.

Fiscal problems have caused entire civilizations to crumble, so cost containment is most assuredly a substantial governmental interest. As such, cost

containment suffices to satisfy the first prong of the *Central Hudson* test.

The next question – whether the law directly advances that interest – is not so cut and dried. To succeed on this prong of the test, the state “must demonstrate that the harms it recites are real and that [the] restriction will in fact alleviate them to a material degree.” *Edenfield*, 507 U.S. at 770-71, 113 S.Ct. 1792. Speculation, surmise, or fevered imaginings will not carry the day. *Id.* at 770, 113 S.Ct. 1792.

This does not mean, however, that certitude is required. A state need not go beyond the demands of common sense to show that a statute promises directly to advance an identified governmental interest. See, e.g., *Burson v. Freeman*, 504 U.S. 191, 211, 112 S.Ct. 1846, 119 L.Ed.2d 5 (1992). While empirical data must plausibly point to a conclusion, that data need not be “accompanied by a surfeit of background information.” *Florida Bar*, 515 U.S. at 628, 115 S.Ct. 2371. States are allowed “to justify speech restrictions by reference to studies and anecdotes” or even to justify them “based solely on history, consensus, and simple common sense.” *Id.* (internal quotation marks omitted).

Here, the state’s evidence falls into three evidentiary subsets, each of which forges some part of the causal chain leading from transfers of prescribers’ histories for use in detailing to higher drug prices.

The first category embodies evidence showing that detailing increases the cost of prescription drugs.

The second involves a showing that prescribers' histories enhance the success of detailing. The final category encompasses evidence indicating that, notwithstanding these escalating costs, detailing does not contribute to improved patients' health. Drawing these inferences, the state reasons that stripping detailers of the ability to use prescribers' histories as a marketing tool will decrease the quantities of (relatively expensive) brand-name drugs dispensed, increase the quantities of (relatively inexpensive) generic drugs dispensed, and thus reduce or contain overall costs. The plaintiffs respond with evidence of the positive effects of detailing enhanced by prescribers' histories and by noting that the state has not proven that health care costs will ebb following increased substitution of generic drugs for brand-name drugs.

The state's initial point is unarguable: pharmaceutical companies use detailing to promote the sale of brand-name drugs, and those drugs cost significantly more than their generic counterparts.⁷ Detailing works: that it succeeds in inducing physicians to prescribe larger quantities of brand-name drugs seems clear (even if the exact magnitude of that effect

⁷ Of course, targeted detailing is employed not only to promote the sale of brand-name drugs in lieu of generic drugs, but also to encourage prescribers to choose one particular brand-name drug over another. The latter situation is not the state's primary concern because the cost differential between competing brand-name drugs is less likely to be significant.

is not). See, e.g., Puneet Manchanda & Elisabeth Honka, *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An integrative Review*, 5 Yale J. Health Pol'y L. & Ethics 785, 809 (2005); Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 J. Am. Med. Ass'n 373, 378 (2000). The fact that the pharmaceutical industry spends over \$4,000,000,000 annually on detailing bears loud witness to its efficacy.

The testimony adduced at trial reinforced these common-sense conclusions. Dr. Jerome Avorn, a professor at Harvard Medical School specializing in pharmacoepidemiology and pharmacoeconomics, described studies showing that detailing substantially increases physicians' rates of prescribing brand-name drugs. This account echoed testimony of the president and president-elect of the New Hampshire Medical Society.

The evidence in support of the second step in the progression – that detailing becomes incrementally more successful when pursued with the aid of physician-specific prescribing histories – is less formidable. Still, Dr. Avorn drew analogies to opine that detailers armed with prescribing histories enjoyed a significant marketing advantage, resulting in greater leverage, increased sales of brand-name drugs, and higher drug costs – all with no corresponding benefit to patients. In addition, a former detailer, relying on personal experience, testified about various kinds of leverage that prescribing histories afforded detailers (e.g., the

ability to target physicians prescribing large quantities of generic drugs, the ability to zero in on a physician's customary prescribing choices, and the ability to punish physicians who fail to display allegiance to particular brand-name drugs). Each of these witnesses emphasized that prescribing histories helped the detailer to become more adversarial in her presentation and to focus on the weakness of the physician's erstwhile drug of choice as opposed to the clinical virtues of the detailed drug. A promotional brochure published by IMS for detailers' use corroborated many of these claims, as did a submitted newspaper article that formed part of the legislative history underlying the Prescription Information Law. See Liz Kowalczyk, *Drug Companies' Secret Reports Outrage Doctors*, Boston Globe, May 25, 2003, at A1.

The plaintiffs did not deny that prescribing histories made detailing more efficacious. They did, however, try to cast detailing as a helpful and informative activity. In their view, prescribing histories enable detailers both to target the physicians most likely to benefit from an educational interaction and to craft a marketing message tailored to the physician's practice. The plaintiffs offered the testimony of Dr. Thomas Wharton, a distinguished cardiologist, to support this characterization. Dr. Wharton found detailing to produce highly informative interactions in which "the level of discourse is elevated." Other testimony indicated that the availability of prescribing histories permitted detailers to inform physicians more quickly of negative information. Finally, the

plaintiffs adduced evidence anent the purported value of identifying and targeting "early adopters."

The district court determined that the state's asserted cost containment interest failed to satisfy the second prong of the *Central Hudson* test. The court based this determination on its conclusion that the final link in the chain of reasoning was missing: "[t]he Attorney General appears to assume that any health care cost savings that will result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care." D. Ct. Op., 490 F.Supp.2d at 180. This assumption was flawed, the court wrote, because brand-name drugs sometimes served patients better than their generic counterparts; thus, it was possible that an increase in generic drug prescriptions might compromise patient care, engender new medical costs, and overwhelm any savings. *Id.* at 180-81.

Admittedly, the state's showing that health care costs would lessen should prescriber histories be denied to detailers was not overwhelming. But even though there was no direct evidence on that point, the state did present unrebutted testimony to the effect that detailing tended dramatically to increase the prescription of brand-name drugs (and, thus, the cost of prescription drugs) without conferring any corresponding public health benefit. This was the opinion of Dr. Avorn, and Dr. Wazana's article reached the same conclusion. See Wazana, *supra*, at 375. The record also contains evidence of widespread incidents – Vioxx and calcium channel blockers are

two prominent examples – that pointed in the same direction. Finally, the record contains a study that found that 11% of detailers' statements to physicians were demonstrably inaccurate.⁸ See M.G. Ziegler, P. Lew & B.C. Singer, *The Accuracy of Drug Information from Pharmaceutical Sales Representatives*, 273 J. Am. Med. Ass'n 1296 (1995).

In the face of this highly suggestive evidentiary predicate, the district court's demand that the state prove that the substitution of generic drugs for brand-name drugs would not lead to higher net health care costs subjected the state to a level of scrutiny far more exacting than is required for commercial speech. See *City of Renton v. Playtime Theatres, Inc.*, 475 U.S. 41, 51, 106 S.Ct. 925, 89 L.Ed.2d 29 (1986) (permitting city to rely on experiences of different localities); *Nat'l Amusements*, 43 F.3d at 742 (permitting town to rely on residents' complaints, "constabulatory concern with a pattern of incidents," and common sense). The state provided competent evidence that detailing increases the prescription of brand-name drugs, that brand-name drugs tend to be more expensive, that detailers' possession of prescribing histories heightens this exorbitant effect, that many aggressively detailed drugs provide no benefit vis-à-vis their far

⁸ The plaintiffs responded to this study by citing the federal Food and Drug Administration regulations prohibiting false medical advertisements. See 21 C.F.R. § 202.1. That response is a non-sequitur. The fact that certain behavior is prohibited by law is not a guarantee that persons will not engage in it.

cheaper generic counterparts, and that detailing had contributed to pharmaceutical scandals endangering both the public health and the public coffers. Viewed against that background, the fact that some detailed brand-name drugs may produce superior results in some cases is too flimsy a hook on which to hang a conclusion that a decrease in the prescription of brand-name drugs would be unlikely to yield a net diminution in health care costs. While the state's position is not ironclad, the district court's objection to it partakes of a far greater degree of conjecture.

In the last analysis, this is more a matter of policy than of prediction. Just as some brand-name drugs produce superior results when compared to generic drugs, some generic drugs produce superior (or, at least, equal) results when compared to brand-name drugs. The record contains substantial evidence that, in several instances, detailers armed with prescribing histories encouraged the overzealous prescription of more costly brand-name drugs regardless of both the public health consequences and the probable outcome of a sensible cost/benefit analysis. By way of contrast, the record contains no evidence that in the absence of detailing, physicians have tended to prescribe generic drugs more often than either their patients' health or their patients' pocket-books warranted. The district court seems to have overlooked this dichotomy.

Perhaps more important, the court appears to have disregarded the constraints under which states operate in formulating public policy on cutting-edge

issues. New Hampshire was the first state to deny detailers access to prescribing histories. Had other states been in the vanguard, it might be permissible to take New Hampshire to task for not presenting studies relative to the law's effect on net health care costs. But to demand such evidence from the first state to refuse detailers access to prescribing histories is to demand too much: that evidence simply does not exist. The First Amendment requires states to assess their own interests realistically and to take only reasonable steps in furtherance of these discerned interests; it does not require Augean feats in order to sustain regulations restricting commercial speech.

The short of the matter is that while a state legislature does not have unfettered discretion "to suppress truthful, nonmisleading information for paternalistic purposes," 44 *Liquormart*, 517 U.S. at 510, 116 S.Ct. 1495, there is in this area "some room for the exercise of legislative judgment," *id.* at 508, 116 S.Ct. 1495. We are duty bound to grant the New Hampshire legislature such elbow room here.

To this we add that, as Justice Brandeis famously observed, "[i]t is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311, 52 S.Ct. 371, 76 L.Ed. 747 (1932) (Brandeis, J., dissenting). That is the case here – and we must allow the state legislature some leeway to experiment with different

methods of combating a social and economic problem of growing magnitude.

At this point, the plaintiffs interpose yet another potential roadblock: they urge us to withhold deference to the legislature's choice of goals and measures in light of the thinness of the legislative record and the relative celerity (four months) with which the legislature acted. They compare New Hampshire's legislative record to the legislative record granted deference by the Supreme Court in *Turner Broadcast System v. FCC*, 520 U.S. 180, 199, 117 S.Ct. 1174, 137 L.Ed.2d 369 (1997) (noting that the congressional record included "years of testimony and reviewing volumes of documentary evidence and studies offered by both sides" compiled three years of hearings).

This is a red herring. It is fanciful to suggest that the congressional record in *Turner* represents the threshold for deference. Furthermore, the plaintiffs' argument converts the issue of deference into a mechanical counting of days and pages. We flatly reject this myopic approach. After all, deference is a matter of degree. Here, we defer to the New Hampshire legislature only on the narrow question of whether it is sensible to conclude (hypothetically) that net medical outlays will decrease as a result of the withdrawal of prescribing histories from detailers. Given the contents of the legislative record, we believe that deference is in order.

We need not probe this point more deeply. In the end, we conclude that the state adequately demonstrated that the Prescription Information Law is reasonably calculated to advance its substantial interest in reducing overall health care costs within New Hampshire.

This leaves the third *Central Hudson* question: whether the regulation is no more extensive than necessary to serve the state's interest in cost containment. The Supreme Court has explained that this standard requires the restriction to be "in reasonable proportion to the interest served." *Edenfield*, 507 U.S. at 767, 113 S.Ct. 1792. More recently, the Court applied a gloss, stating that "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Thompson*, 535 U.S. at 371, 122 S.Ct. 1497.

Invoking *Thompson*, the district court concluded that New Hampshire's goal of cost containment could have been achieved by three alternative measures, none of which would have restricted speech. D. Ct. Op., 490 F.Supp.2d at 181-83. On that basis, the court found that the third prong had not been met.

Our starting point is well-marked: "If the First Amendment means anything, it means that regulating speech must be a last – not first – resort." *Thompson*, 535 U.S. at 373, 122 S.Ct. 1497. This does not mean, however, that a state must forgo legitimate regulatory goals merely because an objector can

hypothesize alternative measures of doubtful efficacy that would leave speech unencumbered.

In this instance, the district court seems to have overestimated the extent to which the alternatives it described were geared to accomplish the state's objective. The Prescription Information Law was a targeted legislative response to a particular problem that had proven resistant to a number of different regulatory approaches. The three measures embraced by the district court were no improvement on those ineffectual approaches.

The first of the measures comprises a ban on gifts between detailers and physicians. Such a measure would target a harm that the legislature never deemed central to its aims. Some studies do indicate that detailers' gifts influence prescribing behavior, but the New Hampshire legislature only saw such gift-giving as pernicious when it occurred within the context of a high-intensity sales pitch made possible by a detailer's possession of a physician's prescribing history. Moreover, such a ban would have unintended consequences; it would necessarily cut off the flow of free samples that physicians receive from detailers and often dispense to indigent patients. New Hampshire was constitutionally entitled to attempt to regulate detailing without killing this golden goose.

The second measure comprises an envisioned campaign to educate physicians to prescribe generic drugs whenever possible. This suggested measure fails as a matter of simple economics. Pharmaceutical

companies spend over \$4,000,000,000 per year on detailing. Against that marketing juggernaut, the state would need to commit enormous resources to put across a contrary message. It is not a ground for striking down a commercial speech regulation that some counter-informational campaign, regardless of the cost, might restore equilibrium to the marketplace of ideas. See *Posadas de P.R. Assocs. v. Tourism Co.*, 478 U.S. 328, 344, 106 S.Ct. 2968, 92 L.Ed.2d 266 (1986).

The third measure hinges on the thought that it would be workable for New Hampshire to retool its Medicaid program so that non-preferred drugs – such as expensive brand-name drugs for which non-bioequivalent generic substitutes exist – would only be dispensed upon a physician's consultation with a pharmacist. See *D. Ct. Op.*, 490 F.Supp.2d at 182. This suggested measure fails for impracticability, for incompleteness, and for coming too late in the prescription process. Implementing it would take extra time out of a doctor's day and, in all events, would make no inroads with respect to privately insured patients. And finally, this third measure represents a crude attempt to remedy the compromised prescribing habits of physicians after the fact. We explain briefly.

Physicians prescribe medications for individuals on the basis of a multitude of factors. A generic drug – whether or not bioequivalent – will rarely be capable of being recommended across the board as a substitute for a brand-name drug because each drug offers

subtly different situation-specific advantages. The physician must attend to the patient's individual symptoms, make a diagnosis, and prescribe accordingly. Detailing provably skews physicians toward prescribing more brand-name drugs by highlighting strengths of brand-name drugs unrelated to the patient's individual condition. Inserting one more laborious step into the decisionmaking process may incline physicians to prescribe fewer brand-name drugs and more generic drugs; but it will do nothing to correct for or efface the distorting factors previously introduced into the physician's prescribing habits. The New Hampshire legislature enacted the Prescription Information Law not only to lower costs but also to prevent detailers from exerting so much influence over physicians' prescribing habits.

In sum, we find that neither the plaintiffs nor the district court has identified an alternative to the Prescription Information Law that promises to achieve the goals of the law without restricting speech. Consequently, we hold that the Prescription Information Law is no more restrictive than necessary to accomplish those goals.

That ends our First Amendment inquiry. For the reasons elucidated above, we hold that the challenged portions of the Prescription Information Law survive the rigors of intermediate scrutiny. Thus, even if one assumes that those provisions to some extent implicate commercial speech, they do not violate the First Amendment.

VII. VOID FOR VAGUENESS

Terming numerous undefined words and phrases in the Prescription Information Law amorphous or ambiguous, the plaintiffs contend that the statute is unconstitutionally vague.⁹ This contention need not detain us.

The pertinent statutory text is set out earlier in this opinion, *see supra* Part II, and it would serve no useful purpose to repastinate that ground. It suffices to say that the plaintiffs question virtually everything from soup to nuts – from the meaning of the adjective “identifiable” to the scope of the phrase “commercial purpose.” They allege that this pervasive imprecision chills protected speech (especially since violations of the statute may trigger both criminal and civil penalties). *See Reno v. ACLU*, 521 U.S. 844, 872, 117 S.Ct. 2329, 138 L.Ed.2d 874 (1997).

We readily acknowledge that the Prescription Information Law is not a model of legislative craftsmanship. But statutes do not need to be precise to the point of pedantry, and the fact that a statute requires some interpretation does not perforce render it unconstitutionally vague. *See Ridley v. Mass. Bay Transp. Auth.*, 390 F.3d 65, 93 (1st Cir.2004). That is the case here.

⁹ The plaintiffs mention in passing that the Prescription Information Law is overbroad but they do not develop an overbreadth argument. Any such argument is, therefore, waived. *See United States v. Zannino*, 895 F.2d 1, 17 (1st Cir.1990).

A federal court may interpret state law by using the same method and approach that the state's highest court would use. See *Nat'l Pharms., Inc. v. Feliciano-de-Melecio*, 221 F.3d 235, 241-42 (1st Cir.2000); see also *Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 930 (9th Cir.2004) ("Ordinarily, in construing a state statute, we follow the state's rules of statutory interpretation.").

Under New Hampshire law, an inquiring court may consider legislative history to aid in clarifying an ambiguous statute. *Hughes v. N.H. Div. of Aero.*, 152 N.H. 30, 871 A.2d 18, 26 (N.H.2005). The objective is to construe a statute "in light of the legislature's intent in enacting [it], and in light of the policy sought to be advanced by the entire statutory scheme." *Carlisle v. Frisbie Mem. Hosp.*, 152 N.H. 762, 888 A.2d 405, 417 (N.H.2005). Consistent with that approach, an inquiring court should not hesitate to "presume any narrowing construction or practice to which the law is fairly susceptible." *City of Lakewood v. Plain Dealer Publ'g Co.*, 486 U.S. 750, 770 n. 11, 108 S.Ct. 2138, 100 L.Ed.2d 771 (1988) (internal quotation marks omitted); see *Stenberg v. Carhart*, 530 U.S. 914, 944-45, 120 S.Ct. 2597, 147 L.Ed.2d 743 (2000); *R.I. Ass'n of Realtors, Inc. v. Whitehouse*, 199 F.3d 26, 36 (1st Cir.1999).

Read in light of the legislature's manifest intent, the Prescription Information Law is sufficiently clear to withstand the plaintiffs' vagueness challenge. The legislature's avowed intent was to curtail in New Hampshire what it viewed as the pernicious practice

of targeted detailing by pharmaceutical companies. It sought to do so by prohibiting "for any commercial purpose" the dissemination and use of the data on which targeting had come to depend: prescriber histories. In keeping with this narrow purpose, the statute excludes from its coverage almost every commercial use other than detailing; the listed exemptions include "pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research or as otherwise provided by law." N.H.Rev.Stat. Ann. § 318:47-f.

As we understand the state's position, these categories of exceptions are to be construed broadly to avoid impinging upon uses of prescriber-identifiable data that do not implicate the state's core concern. For example, the Attorney General explicitly acknowledged in the court below that the Prescription Information Law does not bar the plaintiffs from selling prescriber-identifiable data to pharmaceutical companies for research or for recruiting physicians to participate in clinical trials of newly developed drugs. Given that understanding, the fact that data derived from such research or trials later may be used in the companies' general marketing cannot transform the permitted uses into ones that have an impermissible purpose. After all, marketing and sales are the ultimate purposes for virtually all research done by pharmaceutical companies. As long as the companies do not undertake targeted detailing of New

Hampshire-based clinical trial participants – whose prescribing data was obtained for research purposes – there is no violation of the Prescription Information Law.

We recognize that this construction of the Prescription Information Law is not inevitable. But this is a facial challenge, and the state's articulated purpose narrows the interpretive lens through which we must view the problem. *See Davis v. FEC*, ___ U.S. ___, 128 S.Ct. 2759, 2770-71, 171 L.Ed.2d 737 (2008) (noting that in facial challenges courts should “extend[] a measure of deference to the judgment of the legislative body that enacted the law”); *Wash. State Grange v. Wash. State Repub. Party*, ___ U.S. ___, 128 S.Ct. 1184, 1194, 170 L.Ed.2d 151 (2008) (explaining that deference requires an inquiring court to ask whether challenged law could possibly be implemented constitutionally). This perspective requires us to give the exceptions their full scope and eliminates any chilling effect. Health care professionals who use prescriber-identifiable data to influence physician prescribing decisions other than through direct marketing need not be concerned that their activity will offend the statute.

This narrow reading of the Prescription Information Law similarly serves to allay concerns that pharmacies and other sources of prescriber data will be subject to prosecution based on some improper downstream use of that data. As long as such entities impose conditions on the transfer of such data that require purchasers to comply with the terms of the

law, they are safe. Thus, when data is requested for one of the myriad uses that are permissible under the Prescription Information Law, there should be no chilling effect.¹⁰

For these reasons, we reject the plaintiffs' contention that the law is void for vagueness.

VIII. DORMANT COMMERCE CLAUSE

Finally, the plaintiffs mount a Commerce Clause challenge to the Prescription Information Law. They maintain that the statute violates the Constitution by regulating conduct wholly outside New Hampshire. This argument is unavailing.

The Commerce Clause, ostensibly an affirmative grant of power to Congress "[t]o regulate Commerce . . . among the several states," U.S. Const. art. I § 8 cl. 3, embodies a negative aspect that "prevents state and local governments from impeding the free flow of goods from one state to another." *Alliance of Auto. Mfrs. v. Gwadosky*, 430 F.3d 30, 35 (1st Cir.2005) (quoting *Houlton Citizens' Coal. v. Town of Houlton*, 175 F.3d 178, 184 (1st Cir.1999)). The proper mode of analysis under this so-called "dormant Commerce Clause" depends upon the scope of the challenged

¹⁰ Because no pharmaceutical company is a party to this litigation, we decline to address whether an action could be maintained under the Prescription Information Law against a pharmaceutical company that uses data properly acquired for one purpose to target physicians for detailing.

statute. See *id.* A law that purports to regulate conduct occurring wholly outside the enacting state "outstrips the limits of the enacting state's constitutional authority and, therefore, is per se invalid." *Id.*; see *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 79 (1st Cir.2001), *aff'd*, 538 U.S. 644, 123 S.Ct. 1855, 155 L.Ed.2d 889 (2003). This is the principle that the plaintiffs see as controlling here.

Their argument runs along the following lines. They point out that the New Hampshire law lacks any explicit mention of a geographic limitation. Building on this foundation, they invite us to hold that the N.H.Rev.Stat. Ann. § 318:47-f. prohibits the licensing, transfer, use, and sale of prescriber-identifiable data everywhere, (including transactions that take place wholly outside New Hampshire). So interpreted, the statute would, among other things, prohibit the transfer of data from a pharmacy benefits manager located in, say, New York to Verispan, a Delaware firm headquartered in Pennsylvania. Such a direct regulation of out-of-state transactions would, the plaintiffs assert, be per se invalid under the dormant Commerce Clause. See *Alliance of Auto. Mfrs.*, 430 F.3d at 35.

For its part, the state urges us to interpret the law as governing only in-state transactions. As we already have explained, a federal court normally should interpret state law using the same method and approach that the highest court of the state would use. See *Nat'l Pharms.*, 221 F.3d at 241-42.

An assertion that the Commerce Clause invalidates a particular statutory scheme presents a facial challenge to that statute. *See generally United States v. Nascimento*, 491 F.3d 25, 41 (1st Cir.2007) (distinguishing facial and as-applied Commerce Clause challenges to federal law), *cert. denied*, ___ U.S. ___, 128 S.Ct. 1738, 170 L.Ed.2d 543 (2008). "[I]n evaluating a facial challenge to a state law, a federal court must . . . consider any limiting construction that a state court or enforcement agency has proffered." *McGuire v. Reilly*, 386 F.3d 45, 58 (1st Cir.2004) (quoting *Ward v. Rock Against Racism*, 491 U.S. 781, 795-96, 109 S.Ct. 2746, 105 L.Ed.2d 661 (1989)). This same deference obtains in the courts of New Hampshire. *See In re Morgan*, 144 N.H. 44, 742 A.2d 101, 109 (N.H.1999) (counseling deference to administrative interpretations of statutes unless such an interpretation is "plainly incorrect").

Two additional principles of statutory interpretation figure into the equation. First, state statutes should be presumed to govern only conduct within the borders of the enacting state. *See K-S Pharms., Inc. v. Am. Home Prods. Corp.*, 962 F.2d 728, 730 (7th Cir.1992); *State v. McGlone*, 96 N.H. 448, 78 A.2d 528, 530 (N.H.1951). Second, statutes should be given a constitutional as opposed to an arguably unconstitutional interpretation whenever fairly possible. *See Arizonans for Official English v. Arizona*, 520 U.S. 43, 78, 117 S.Ct. 1055, 137 L.Ed.2d 170 (1997); *Nascimento*, 491 F.3d at 38; *see also Sibson v. State*, 110

N.H. 8, 259 A.2d 397, 400 (N.H.1969) (explaining that "a statute will be construed to avoid a conflict with constitutional rights whenever that course is reasonably possible").

Here, the New Hampshire Attorney General – the state official charged with enforcing its laws – has exhorted us to read the Prescription Information Law to "relate only to activity that takes place domestically." Appellant's Reply Br. at 13. This narrowing construction is reasonable and accords with the tenet that laws should not be presumed to have extraterritorial effect. It also avoids any doubt about the law's constitutionality under the dormant Commerce Clause. As the Seventh Circuit wisely observed when confronted with a similar state statute lacking any built-in geographic restriction, it would make no sense to read the statute to regulate out-of-state transactions when the upshot of doing so would be to annul the statute. *See K-S Pharms.*, 962 F.2d at 730.

There is no need to belabor the point. We are confident that the New Hampshire Supreme Court would interpret the Prescription Information Law to affect only domestic transactions. Seen in this light, the plaintiffs' dormant Commerce Clause challenge necessarily fails. This law may result in a loss of profit to out-of-state data miners due to the closing of one aspect of the New Hampshire market for their wares, but that circumstance amounts neither to regulating conduct outside the state nor to "necessarily requir[ing] out-of-state commerce to be conducted

according to in-state terms." *Wine & Spirits II*, 481 F.3d at 15.

We add a coda. Our dissenting brother concedes that, on its face, the Attorney General's interpretation of the Prescription Information Law obviates any Commerce Clause problem. He nevertheless suggests that that interpretation leaves the Act with "negligible impact" and is, therefore, unreasonable. We fail to see the logic in this suggestion.

To be sure, the Attorney General's plausible interpretation of the Prescription Information Law, which permits the routine transfer of data to out-of-state facilities where it can then be aggregated and sold legally to others, may not accomplish very much.¹¹ But that does not make the Attorney General's interpretation unreasonable. See *McGuire*, 386 F.3d at 58; *In re Morgan*, 742 A.2d at 109. There is no rule that forbids a legislature from enacting prophylactic legislation to prevent disfavored activity before individuals engage in that activity.

IX. CONCLUSION

We need go no further. For the reasons elucidated above, we reverse the decision of the district court

¹¹ The question remains, however, whether the purchasers could subsequently make use of the aggregated data in New Hampshire. That question is not before us.

and vacate the injunction against enforcement of the Prescription Information Law.

Reversed.

LIPEZ, Circuit Judge, concurring and dissenting.

Although I agree with the majority that the district court's decision cannot stand, I respectfully disagree with the majority's refusal to address the First Amendment issue at the core of this case. The majority focuses on the so-called upstream transactions – the acquisition, aggregation, and sale of prescriber-identifiable data by the plaintiffs – and concludes that such activity is not speech within the purview of the First Amendment. That conclusion is self-evident and beside the point. In enacting the Prescription Information Confidentiality Act (“the Prescription Act” or “the Act”),¹² the New Hampshire Legislature chose to regulate the upstream transactions because it wanted to alter the message used by pharmaceutical detailers in pursuing a downstream transaction with health care professionals. In other words, the Act was designed to limit the speech of those detailers. The majority relies on the prudential doctrine of standing to avoid deciding whether that limitation violates the First Amendment. In my view,

¹² The legislation did not include a formal title for the statute; I have adopted a formulation that blends the district court's and the parties' usage.

that avoidance is wasteful and unwise, unsupported by principles of standing, and analytically flawed.

Consequently, after examining the issue of standing, I address the issue that we should be addressing – whether the Act restricts protected commercial speech between detailers and prescribers and, if so, whether the State can justify that restriction under the commercial speech test of *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980). I conclude that the Act does restrict commercial speech, and that the State's interest in cost containment justifies that restriction. I also conclude, contrary to the majority, that we should remand the case for consideration of the plaintiffs' Commerce Clause challenge.

I.

The majority admits that speech is implicated by the Prescription Act and identifies that speech as "primarily [the] communications between detailers and doctors." It purports to refuse to address the Act's impact on that targeted speech, based on principles of standing, because "no detailer or doctor is a plaintiff here." However, not only do my colleagues misguidedly invoke standing to avoid explicitly resolving the constitutionality of the Act's restriction on communications between detailers and doctors, but they also accept the State's justification for the restriction without allowing the plaintiffs to establish the First

Amendment values at stake. The majority's use of standing principles is thus doubly wrong.

A. The Prudential Policies of Third Party Standing

In *Craig v. Boren*, 429 U.S. 190, 97 S.Ct. 451, 50 L.Ed.2d 397 (1976), the Supreme Court considered whether a beer vendor could challenge on equal protection grounds an Oklahoma statute that prohibited the sale of "nonintoxicating" 3.2% beer to males under 21 and to females under 18. The question was whether the beer vendor had standing to raise the equal protection objections of 18- to 20-year-old males. The Court noted that the plaintiff had the requisite "injury in fact" to satisfy the constitutional standing requirement, *id.* at 194, 97 S.Ct. 451,¹³ leaving only a prudential concern about whether the

¹³ The Court stated there:

The legal duties created by the statutory sections under challenge are addressed directly to vendors such as appellant. She is obliged either to heed the statutory discrimination, thereby incurring a direct economic injury through the constriction of her buyers' market, or to disobey the statutory command and suffer, in the words of Oklahoma's Assistant Attorney General, "sanctions and perhaps loss of license." This Court repeatedly has recognized that such injuries establish the threshold requirements of a "case or controversy" mandated by Art. III.

429 U.S. at 194, 97 S.Ct. 451.

plaintiffs should be allowed to raise third-party constitutional claims.

In concluding that the vendor's claims could go forward, the Court observed that it is "settled that limitations on a litigant's assertion of *jus tertii* are not constitutionally mandated, but rather stem from a salutary 'rule of self-restraint' designed to minimize unwarranted intervention into controversies where the applicable constitutional questions are ill-defined and speculative." *Id.* at 193, 97 S.Ct. 451. However, in the circumstances before the Court in *Craig*, such "prudential objectives" could not be furthered because "the lower court already ha[d] entertained the relevant constitutional challenge and the parties ha[d] sought or at least ha[d] never resisted an authoritative constitutional determination." The Court continued:

In such circumstances, a decision by us to forgo consideration of the constitutional merits in order to await the initiation of a new challenge to the statute by injured third parties would be impermissibly to foster repetitive and time-consuming litigation under the guise of caution and prudence. Moreover, insofar as the applicable constitutional questions have been and continue to be presented vigorously and "cogently," the denial of *jus tertii* standing in deference to a direct class suit can serve no functional purpose.

Id. at 193-94, 97 S.Ct. 451 (citation omitted).

There is no debate that the plaintiffs in this case also meet the requirements for Article III standing. Like the beer vendors in *Craig*, the plaintiffs here are direct targets of the challenged statute. By seeking to prevent pharmaceutical detailers from using prescriber data in their sales pitches to New Hampshire health care providers, the Act diminishes the market for the prescriber data collected, organized and sold by plaintiffs and thereby inflicts "a direct economic injury through the constriction of [the] buyers' market." 429 U.S. at 194, 97 S.Ct. 451. Thus, as in *Craig*, only the prudential standing doctrine is at issue, and here, too, pragmatic considerations are paramount. The district court heard evidence from about a dozen witnesses and considered voluminous other materials in preparing its thoughtful and comprehensive decision. Nothing in the extensive record even hints that the plaintiffs were unable or unwilling to aggressively litigate the First Amendment issues at stake in the "downstream" transactions between the detailers and physicians. Such an inability or unwillingness would counsel prudence in resolving the First Amendment issues raised by those transactions without the participation of the pharmaceutical companies or doctors. But here the First Amendment issues raised by the exchanges between detailers and physicians were explored exhaustively.

Moreover, the district court expressly confronted the question of third-party standing before proceeding with the case. The court told the parties that, if the State sought to invoke standing as a barrier to full

resolution of the action, it would stay the case for thirty days to allow intervention by a pharmaceutical company. The court explained:

[I]t's very clear you are working closely with the pharmacy companies here. They don't want to be the ones to stand up and fight the doctors. They want you to do it. We all know what's going on here, and the reality is if they have to, they will come out from behind the scenes and get out into the forefront, because they want this information, and they want you to be fighting the battle for them. But if we have to, we'll get them in here. *I just don't think it really matters.*

So the state should think about that. If you want to fight on that issue, that's what I would do. I would first do an argument on third-party standing. If I think there's any issue with third-party standing, if the plaintiff asked for it, I will give them 30 days to amend to bring in a new plaintiff pharmacy company, in which case it seems to me the third-party standing argument disappears.

I didn't think we were going to be talking about third-party standing today, since it's not really raised in the briefs now. But if you want to press that, I think we'll have to deal with it that way.

(Emphasis added.) The Attorney General then said that "we don't intend to press that at this time." The issue was not addressed by either party on appeal.

In these circumstances, as in *Craig*, "a decision . . . to forgo consideration of the constitutional merits in order to await the initiation of a new challenge to the statute by injured third parties would be impermissibly to foster repetitive and time-consuming litigation under the guise of caution and prudence." 429 U.S. at 193-94, 97 S.Ct. 451. The prudence invoked by the majority serves no purpose and it ignores the judgment of the district court, based on its immersion in the details of the case, that the absence of the pharmaceutical companies as parties did not compromise the proper adjudication of the case.

I recognize that the Supreme Court's precedent on third-party standing since *Craig*, as well as our own precedent, set out a formal three-prong inquiry that could not be satisfied here because, as the majority observes, there is no indication in the record that pharmaceutical companies or health care providers who prescribe medication are unable to assert their own rights. See, e.g., *Kowalski v. Tesmer*, 543 U.S. 125, 129-30, 125 S.Ct. 564, 160 L.Ed.2d 519 (2004); *Powers v. Ohio*, 499 U.S. 400, 410-11, 111 S.Ct. 1364, 113 L.Ed.2d 411 (1991); *Wine & Spirits Retailers, Inc. v. Rhode Island (Wine & Spirits I)*, 418 F.3d 36, 49 (1st Cir.2005). However, none of those cases suggests that the pragmatic factors emphasized by the Court in *Craig* no longer have force in comparable circumstances.

The prudential limitations on standing were designed to "add to the constitutional minima a healthy concern that if the claim is brought by someone other

than one at whom the constitutional protection is aimed, the claim not be an abstract, generalized grievance that the courts are neither well equipped nor well advised to adjudicate." *Sec'y of State of Md. v. Joseph H. Munson Co.*, 467 U.S. 947, 955 n. 5, 104 S.Ct. 2839, 81 L.Ed.2d 786 (1984); see also *Miller v. Albright*, 523 U.S. 420, 446, 118 S.Ct. 1428, 140 L.Ed.2d 575 (1998) (O'Connor, J., concurring) (stating that the requirement that a litigant assert his own legal rights "arises from the understanding that the third-party rightholder may not, in fact, wish to assert the claim in question, as well as from the belief that 'third parties themselves usually will be the best proponents of their rights'" (citation omitted). The Supreme Court has recognized that the "lessening" of these limitations may be justified where other concerns, such as the danger of chilling free speech, are more pressing, *Munson*, 467 U.S. at 956, 104 S.Ct. 2839, or where, as in *Craig*, such limitations do not serve the purpose for which they were designed.

Indeed, the Court in *Tesmer* conceded that it had been "quite forgiving with the[] criteria [for third-party standing] in certain circumstances," and identified the context of the First Amendment as one in which flexibility may be warranted. *Tesmer*, 543 U.S. at 130, 125 S.Ct. 564. In *Munson*, the Court described its conclusion to allow third-party standing in terms also applicable here: "The activity sought to be protected is at the heart of the business relationship between [the plaintiff] and its clients, and [the plaintiff's] interests in challenging the statute are

completely consistent with the First Amendment interests of the [third parties] it represents. We see no prudential reason not to allow it to challenge the statute." 467 U.S. at 958, 104 S.Ct. 2839. Thus, notwithstanding the Court's more detailed articulation of the third-party standing inquiry since *Craig*, see *Miller*, 523 U.S. at 447, 118 S.Ct. 1428 (O'Connor, J., concurring), the pragmatic considerations highlighted in that decision remain relevant.

This case illustrates the importance of pragmatism. There is no reason to reject the district court's decision to proceed without a pharmaceutical company as a plaintiff unless that decision would result in a trial of the "generalized grievance that the courts are neither well equipped nor well advised to adjudicate," *Munson*, 467 U.S. at 955 n. 5, 104 S.Ct. 2839. The reality is that the court and the parties have expended substantial time, resources and energy to address comprehensively the First Amendment issue at the heart of this case. That issue has been vigorously tried and thoughtfully adjudicated. Given our authority to review the court's entire judgment, it is imprudent to avoid that issue.

B. The Unavoidable Issue

The majority's analysis reveals yet another reason why its reliance on standing is inappropriate. In the first part of its analysis, the majority finds no constitutional flaw in the Act's restriction on "certain information exchanges" because those transfers "are

not . . . the sorts of exchanges valued by the Supreme Court's First Amendment jurisprudence." However, to reach that conclusion, the majority considers the societal benefits of a particular form of detailing – the very *speech* that it claims is beyond the scope of this appeal.

My colleagues insist that the limited scope of review "does not prevent consideration of New Hampshire's interest in combating detailing." I do not understand how the majority can have it both ways. If the constitutionality of the Act's impact on the detailers' speech is off limits in this case because a pharmaceutical company is not a party, how can the majority make a judgment about the low value of that speech in deciding that the Act regulates only conduct and not speech? Surely we must consider the plaintiffs' First Amendment contentions before concluding that the upstream information "exchanges" that make the speech possible are not worthy of First Amendment protection.

This inconsistency pervades the majority's decision. After making judgments about the nature of the detailing transaction and how it increases the likelihood that physicians will prescribe more expensive drugs, the majority asserts that "the legislature sought to level the playing field *not by eliminating speech* but, rather, by eliminating the detailers' ability to use a particular informational asset – prescribing histories – in a particular way." (Emphasis added.) Here the majority is characterizing the speech interest that is supposedly beyond the scope of

its opinion, and characterizing it incorrectly. The very elimination of the detailers' ability to use "a particular informational asset" restricts the message they are allowed to disseminate and implicates the free speech concerns of the First Amendment.

Moreover, in discussing its alternative holding, which treats the plaintiffs' upstream transactions as speech subject to the First Amendment rather than conduct,¹⁴ the majority weighs the value of detailing, based on the regulated data, against the Legislature's policy objectives and the harms identified by the government. Again, the majority's conclusion that the Act does not violate the First Amendment rests on a judgment about the speech – i.e., the detailing – that the majority purports to place off limits for analysis. For example, the majority points to "substantial evidence" in the record

that, in several instances, detailers armed with prescribing histories encouraged the overzealous prescription of more costly brand-name drugs regardless of both the public health consequences and the probable outcome of a sensible cost/benefit analysis. By contrast, the record contains no evidence that in the absence of detailing, physicians have tended to prescribe generic drugs more

¹⁴ The majority never actually identifies the specific speech component of the acquisition, aggregation and sale of information from pharmacies to data miners and from data miners to pharmaceutical companies.

often than either their patients' health or their patients' pocketbooks warranted.

The majority ultimately concludes that "the state adequately demonstrated that the Prescription Information Law is reasonably calculated to advance its substantial interest in reducing overall health care costs within New Hampshire."

Thus, the majority does what it says standing doctrine forbids: it evaluates the Act based on the law's impact on the speech between detailers and prescribers. The majority's approach is hardly surprising given that this speech was the Act's target. What is surprising is the majority's failure to appreciate that reliance on standing principles is misplaced where, as here, the issue that the majority seeks to avoid is unavoidable. Although ostensibly limiting its First Amendment inquiry to the upstream transactions – the acquisition, aggregation, and sale of prescriber-identifiable data – and deciding in its primary holding that these transactions involve conduct only, the majority makes judgments about the nature, value, and consequences of the speech that occurs in the downstream transactions between detailers and doctors. As the majority discovered, it is impossible to assess the constitutionality of the Act without factoring in the Legislature's specific objective to limit the speech of the detailers.

Moreover, there is no reason to think that the majority's judgments about the statute would change in a case where a pharmaceutical company was a

plaintiff. All of the relevant considerations were explored by the district court. They have similarly been explored in the majority's analysis because the majority could not characterize the upstream transactions as merely conduct without making judgments about the value of the "downstream" speech between the detailers and the doctors.

Thus, both the practicalities of this litigation and the nature of the First Amendment issue require that the case be analyzed as the parties tried it and the district court decided it. I therefore proceed with that analysis. Although my discussion will at times overlap with the majority's, I have chosen to present my complete view of the record and the governing law. The First Amendment question here is both important and close, and I wish to fully explain why, in the end, I conclude that the district court erred in declaring the Prescription Act unconstitutional.

II.

In recounting the background of this case, I draw heavily on the comprehensive and thoughtful recitation of the facts set out by the district court. See *IMS Health Inc. v. Ayotte*, 490 F.Supp.2d 163, 165-74 (D.N.H.2007). Those facts are largely undisputed; the parties primarily contest their legal significance.¹⁵

¹⁵ The appellees argue that we should apply the deferential clear error standard in reviewing the facts found by the district court, rather than the de novo standard that typically applies in

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A. Pharmaceutical Sales and Marketing

More than three billion prescriptions are written each year by doctors and other licensed health care professionals, covering approximately 8,000 different pharmaceutical products. These prescriptions are filled by approximately 54,000 retail pharmacies; in 2004, such retail prescription sales totaled \$168 billion.¹⁶ In an effort to increase and protect their share of this vast market, pharmaceutical companies engage in various promotional activities. The public is most familiar with direct-to-consumer advertising, in which the drug companies tout the virtues of their products in television commercials and other media,

First Amendment cases, see *Bose Corp. v. Consumers Union*, 466 U.S. 485, 514, 104 S.Ct. 1949, 80 L.Ed.2d 502 (1984), because the court held in favor of the free speech claim. Several circuits have adopted such an approach, see, e.g., *Multimedia Publ'g Co. of S.C., Inc. v. Greenville-Spartanburg Airport Dist.*, 991 F.2d 154, 160 (4th Cir.1993); *Daily Herald Co. v. Munro*, 838 F.2d 380, 383 (9th Cir.1988), while others exercise independent review regardless of the outcome in the district court. Our court has not yet spoken on the issue, see *United States v. Frabizio*, 459 F.3d 80, 97 (1st Cir.2006) (Torruella, J., concurring), but I need not resolve the question here because my disagreement with the district court stems from a different view of the law rather than the facts. Legal issues, as well as mixed questions dominated by legal issues, are subject to de novo review. See *In re PolyMedica Corp. Sec. Litig.*, 432 F.3d 1, 4 (1st Cir.2005).

¹⁶ The number of prescriptions per capita averaged 10.6 in the United States overall; New Hampshire was close to that average, with 10.1 prescriptions per capita. *Trends and Indicators in the Changing Health Care Marketplace*, Kaiser Family Foundation, <http://www.kff.org/insurance/7031/print-secl.cfm>, at 20-21 [hereinafter *Trends and Indicators*].

typically urging consumers to ask their doctors for the advertised drugs. However, the bulk of the drug companies' promotional efforts are aimed directly at physicians and other prescribers.¹⁷ The primary method for such promotion is detailing, which usually is accompanied by the provision of free drug samples that prescribers can distribute to patients.¹⁸ As

¹⁷ The record contains varying reports on the amount that pharmaceutical companies spend on promotion, although the figures consistently are in the billions. For example, a declaration by two experts for the Attorney General, Dr. Jerry Avorn and Dr. Aaron Kesselheim, stated that the industry spent about \$4 billion in 2000 on direct-to-physician strategies. Declaration at 4 (citing Susan Okie, *AMA criticized for letting drug firms pay for ethics campaign*, Wash. Post, Aug. 30, 2001). A 2005 Report by Rep. Henry Waxman to the Democratic Members of the Committee on Government Reform stated that promotions targeting physicians totaled \$5.7 billion in 2003, including advertising in professional journals. Memorandum Re "The Marketing of Vioxx to Physicians," May 5, 2005, at 6 n. 15 (citing Pharmaceutical Research and Manufacturers Ass'n). The Kaiser Family Foundation reported that drug manufacturers spent \$7.8 billion in 2004 on advertising directed toward physicians. See *Trends and Indicators*, *supra*, at 22. The Foundation is a nonprofit organization that provides information and analysis on health care issues to the government, media, health care community and the general public. Finally, a brief submitted by amici (AARP, et al.) cites a New York Times article reporting that drug companies spent \$13.9 billion promoting their products in 1999, most of which was directed toward doctors and other prescribers. Sheryl Gay Stolberg & Jeff Gerth, *High-Tech Stealth Being Used to Sway Doctor Prescriptions*, N.Y. Times, Nov. 16, 2000, at A1.

¹⁸ The companies also place advertisements in medical journals and sponsor meetings in which physicians are recruited
(Continued on following page)

inducements to increase their access to physicians who are sometimes reluctant to meet with them, detailers also frequently offer free meals and other gifts to the doctors and their staffs. As I shall explain, these practices are both widely used and widely criticized.

1. Detailing

Detailing is the face-to-face advocacy of a product by sales representatives who visit doctors' offices and hospitals to meet with the prescribing health care professionals. Although the objective of these visits is to make sales, detailers often provide valuable information about the drugs they are selling. Doctors may be alerted by a detailer to tests showing the risk of a drug interaction or a drug's side effects. One survey showed that most physicians meet with pharmaceutical representatives about four times a month. See Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 J. Am. Med. Ass'n 373, 375 (Jan. 19, 2000). Consumers Union has reported research showing many more encounters: "[T]he average primary care physician interacts with 28 sales representatives each week; the average specialist interacts with 14." Consumers Union, *Prescription for Change*, <http://www.consumersunion.org/pdf/drugreps.pdf> (March 2006) (quoting research

to speak to their colleagues about medical conditions and therapies.

from Health Strategies Group). Whatever the frequency, it is undisputed that pharmaceutical detailing plays a substantial role in the dissemination of information about drugs to physicians.

Detailing focuses primarily on brand-name drugs that are entitled to patent protection. Once a patent expires, competitors may obtain approval to sell generic bioequivalent versions of the drug, which are equally effective for most patients but usually much less expensive than their brand-name counterparts. New Hampshire law provides that pharmacies may substitute a bioequivalent generic drug for a brand-name drug unless the prescriber specifies that the brand-name drug is "medically necessary." N.H.Rev.Stat. Ann. § 318:47-d (2003). Thus, once bioequivalent generic drugs become available, sales of the related brand-name drug tend to fall and detailing is no longer considered a cost-effective marketing technique.¹⁹ However, non-bioequivalent options also are available for some medical conditions, and the drug companies aggressively market to urge physicians to choose their patented brand-name medications over such alternatives. Thus, it is this choice – between a still-under-patent, branded drug and a similar, but

¹⁹ Pharmaceutical manufacturers attempt in various ways to retain the dominance of a brand-name drug. For example, they may create a modified version – such as a new time-release capsule – that will have its own period of patent protection.

biologically different generic medication – that is at the heart of this case.²⁰

As I will discuss below, studies indicate that detailing has “a significant effect on physician prescription behavior.” Puneet Manchanda & Elisabeth Honka, *Symposium-Pharmaceutical Innovation and Cost: An American Dilemma: The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 Yale J. Health Pol’y, L. & Ethics 785, 809 (Summer 2005) (“While there seems to be little consensus about the size of the effect, it is clear that the effect is positive and significant in a statistical sense.”).

2. Samples and Other Perks

Free samples and courtesy gifts are routinely given by detailers as part of their sales visits, and

²⁰ Even “bioequivalent” generic drugs are not identical to their branded counterparts. They are required to demonstrate absorption capability between 80 and 125 percent of the branded version, and variations in absorption may trigger different side effects when patients switch from the brand-name drug to a generic version. In addition, because there may be multiple generic options, a patient may experience different reactions depending upon which generic alternative is dispensed. For some patients, these variations could have significant impact, making continued use of the brand-name drug the best approach. However, as I understand the record, a doctor’s decision to continue prescribing a brand-name drug after its patent has expired is not at issue here because the prescribing choice in that situation is not typically the focus of pharmaceutical detailing.

they are important tools in pharmaceutical marketing. Doctors rely on receiving drug samples that they can distribute to patients who are unable to afford the high cost of some medications.²¹ Keeping office doors open to detailers ensures that the doctors will have a continued supply of samples, and some physicians are therefore reluctant to restrict detailing. Even when drug cost is not an issue, the free samples are helpful to physicians who want to test new remedies before committing to them. A patient's positive results during a trial period may lead to a long-term prescription – the detailer's desired outcome. En route to that objective, however, the free samples have provided access to helpful treatment that patients otherwise may not have received. The cost of the samples distributed annually by pharmaceutical

²¹ During the legislative process leading to adoption of the statute, the president of the New Hampshire Medical Society, Marc Sadowsky, noted the importance of the samples to his psychiatric practice:

Some of the medicines I prescribe are \$8 a pill, \$8-10 a pill. I have patients who are stable on these medicines and then they lose their job, don't qualify for any insurance and I am carrying them to keep them stable. That is, I'm giving them samples. I have to sign for the samples every time I get them. So, when the drug reps come in, I have to talk to them. . . . So, I think it is kind of an important thing because these medicines can cost people thousands of dollars a year and I have a good number of citizens of New Hampshire that I am giving free samples to. . . .

representatives has been estimated at more than \$11 billion.²²

It is not only the patients who benefit from the drug companies' largess, however. Physicians and other medical office staff members frequently receive "good will" gifts from detailers, including office supplies, free meals, and conference travel funding – perks that are designed to encourage long-term relationships with, and loyalty toward, the detailers.²³

²² The parties' Second Amended Joint Stipulation of Facts ("Stipulation of Facts") used this figure; the Kaiser Family Foundation reported that the retail value of drug samples provided in 2004 was \$15.9 billion. See *Trends and Indicators*, *supra*, at 22.

²³ As an example, a nurse-practitioner who was the director of a hospital-based cholesterol management center testified at a committee hearing on the New Hampshire law that one drug representative offered to bring coffee and bagels to the center every Tuesday in exchange for "two prescriptions every week." Legislative History, at 41 (hereinafter Legis. Hist.) (testimony of Carolyn Finocchiaro).

A similar anecdote was described in a 2006 New York Times article that also was included in the Legislative History. The article reported that a district manager for a pharmaceutical company sent an e-mail to detailers stating:

"Our goal is 50 or more scripts per week for each territory. If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs and past [consulting arrangements] that you have provided or paid for and get the business!! You can do it!!"

(Continued on following page)

Studies have shown that these sorts of gifts can have a subtle effect on physicians,²⁴ and, because they typically are unrelated to the provision of medical care, they have come under particular fire by both consumer advocates and medical professionals themselves. The Pharmaceutical Research and Manufacturers of America ("PhRMA") in 2002 adopted a voluntary code governing interactions with health care professionals that discourages such inducements

unless either the value of what is provided is insubstantial (less than \$100) and the inducement is primarily for the benefit of patients, or the value of the inducement is minimal and the inducement is directly related to the provider's practice. For example, an occasional gift of a stethoscope is acceptable under the Code because it is not deemed to be of substantial value and the gift benefits patients. In contrast, an unrestricted gift certificate to a local bookstore may not be offered under the Code regardless of its value because it does not benefit patients and is

Gardiner Harris & Robert Pear, *Drug Maker's Efforts to Compete in Lucrative Insulin Market are Under Scrutiny*, N.Y. Times, Jan. 28, 2006.

²⁴ Although studies show that physicians have a "mostly negative" attitude toward gifting, the studies also report that such gifts "induce reciprocal feelings among physicians." Manchanda & Honka, 5 Yale J. Health Pol'y, L. & Ethics, at 809; see also Jason Dana & George Loewenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 J. Am. Med. Ass'n 252, 252-54 (July 9, 2003).

unrelated to the health care professional's practice. The Code draws similar distinctions with respect to meals and entertainment.

490 F.Supp.2d at 168-69 (citations omitted).²⁵

3. Data Mining and Prescriber Profiles

When detailers enter medical offices to market their products, they are equipped not only with detailed information about the drugs they are attempting to sell but also with considerable knowledge about their audience. Much of that prescriber information is supplied by the plaintiffs and similar companies, who play a crucial behind-the-scenes role in the flirtation between pharmaceutical sales representatives and prescribers.²⁶ These so-called "data

²⁵ In 2007, a health care consumer advocacy group based in Boston, Community Catalyst, and the Institute on Medicine as a Profession, a research group at Columbia University, announced a national campaign calling for restrictions on the interaction between doctors and pharmaceutical companies. Stephanie Saul, *Doctors and Drug Makers: A Move to End Cozy Ties*, N.Y. Times, Feb. 12, 2007, at C10. A number of medical centers, including those at Yale, the University of Pennsylvania and Stanford, have announced restrictions on gifts and other interactions between their staff members and the pharmaceutical industry. Some states, including Maine, Vermont and Minnesota, have passed laws either prohibiting gifts to doctors from drug companies or requiring disclosure of the gifts. *Id.*; see Me.Rev.Stat. Ann. tit. 22, § 2698-A (2004) (disclosure); Minn.Stat. § 151.461 (1994) (prohibition); Vt. Stat. Ann. tit. 18, § 4632 (2007) (disclosure).

²⁶ The Stipulation of Facts states that plaintiffs IMS Health Inc. and Verispan LLC "are the world's leading providers of
(Continued on following page)

mining" companies collect and organize information about doctors and their prescribing patterns, converting information gleaned from "thousands of sources" into a commodity for which the pharmaceutical industry pays substantial sums.²⁷ From retail pharmacies and other entities, such as insurers, that acquire the data as part of the business they conduct, the data miners obtain information on every pharmaceutical sale, including the form, strength and dosage of the drug, the amount dispensed, and the name and address of the prescriber. The information includes an identifying code for each patient, although the patient is not personally identified. From other sources, including the American Medical Association, the plaintiffs obtain information about individual prescribers and their specialities.²⁸

The data mining companies weave the information together to produce, among other databases, "prescriber profiles" – individualized reports on the prescriptions being written by particular doctors. The information is then sold to third parties for various commercial uses, including pharmaceutical

information, research and analysis to the pharmaceutical and healthcare industries."

²⁷ According to the Stipulation of Facts, these sources are: pharmaceutical wholesalers, pharmacies, physicians, hospitals and clinics.

²⁸ The AMA's Physician Masterfile contains demographic, educational, certification, licensing and speciality information for more than 800,000 active U.S. medical doctors and more than ninety percent of practicing osteopathic doctors.

marketing, and also is provided at no charge for nonprofit purposes, such as academic and medical research.²⁹ The data provide a historical view of a physician's prescribing practices, allowing the pharmaceutical companies to identify doctors who have displayed a willingness to try new products (the "early adopters") and to target doctors whose drug choices they seek to change. With knowledge of the physicians' prescribing history, the detailers are able to tailor their messages to those doctors' specific circumstances – for example, emphasizing the potential side effects of a competitor's brand-name product that the detailer knows the doctor has been using, or highlighting the advantages of the detailers' branded drug over the generic alternative the doctor routinely prescribes. The detailer's verbal message in favor of the brand-name drug may be furthered by the provision of free samples of the medication, encouraging what is initially a "no-cost" switch to the more expensive drug. The companies also use reports obtained shortly after detailing visits to assess whether the sales calls had an effect on the targeted prescribers' drug choices. The detailer's compensation is sometimes tied to the success of his or her efforts.

²⁹ Pharmaceutical companies also have non-marketing uses for the prescriber-identified data, including to "[d]etermine which products to develop and license," to "[i]mplement prescription recall programs," and to accelerate the development of new drugs based on "the needs and habits of those whose health these new drugs are designed to improve." Stipulation of Facts, at 4-5.

This use of prescriber-identified data has drawn sharp criticism on many fronts, including among physicians who object both to the disclosure of information they deem confidential and to the hard-sell messages delivered by detailers who may know more about their prescribing habits than do the doctors themselves. In 2006, the AMA responded to the concerns by initiating the Prescribing Data Restriction Program ("PDRP"), which allows physicians to restrict access to their prescribing data by pharmaceutical detailers. The AMA also developed guidelines for the use of prescribing data "to provide ethical guidance to the healthcare industry." The guidelines urge that companies, inter alia, "[c]ontinually reinforce that use of prescribing data to overtly pressure or coerce physicians to prescribe a particular drug is absolutely an inappropriate use." Neither the PDRP nor the guidelines have quelled the concerns. The PDRP has been criticized because prescriber information will be withheld only if doctors affirmatively opt out, and the opt-out choice must be renewed every three years. Voluntary guidelines are seen as insufficient to offset the commercial incentives to use the information. Some states, like New Hampshire, turned to legislation to address the concerns.

B. New Hampshire's Statutory Response

The Prescription Act prohibits the transmission or use of both patient-identifiable and prescriber-identifiable data for certain commercial purposes.³⁰ Violators are subject to both criminal and civil penalties. N.H.Rev.Stat. Ann. § 318:55. In pertinent part, the statute provides:

Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the

³⁰ Plaintiffs have not challenged the restrictions on patient-identifiable data.

effectiveness of a professional pharmaceutical detailing sales force.

In effect, the statute prohibits the use of prescriber-identifiable data for all purposes related to detailing, but seeks to preserve access to the data for other uses – including other commercial purposes.³¹ I agree with the district court that the prohibited uses are narrowly defined and that the statute does not, for example, prohibit pharmaceutical companies from using prescriber-identifiable data for their own research. *See* 490 F.Supp.2d at 171.³²

1. Legislative History

In introducing the proposed legislation at a hearing before the Senate Committee on Executive Departments and Administration, Representative Cindy Rosenwald, one of the statute's co-sponsors, explained that it had two goals: "It will protect privacy and it will save money for the state, for consumers and businesses. It will accomplish these goals by prohibiting the sale or use of individual patient or prescriber identity for marketing brand name

³¹ The Act also permits the continued use of aggregated prescriber data, categorized by speciality, zip code and geographic region, but without prescriber identification.

³² Indeed, on the first day of trial, counsel for the Attorney General agreed that pharmaceutical companies could use the prescriber information to recruit physicians to participate in clinical trials.

prescription drugs." A written attachment to her testimony, which included a section entitled "What H.B. 1346 will do," states that the law will, inter alia, "[h]opefully reduce the prescription drug costs for patients, employers & the State Medicaid program."

About sixteen individuals testified at the hearing.³³ A representative of the Department of Health and Human Services, Gregory Moore, emphasized both the privacy and cost reduction purposes of the legislation. He described the prescriber data as the physicians' "trade secrets" and further stated:

The Department also believes that these activities ultimately drive up the cost of prescription drugs and the cost of health care in the aggregate. Since no other state has passed legislation like this, it would be hard for us to quantify what that impact might be, but I find it unlikely the drug companies are sending details into doctors' offices for the purpose of selling doctors cheaper medication. In fact, I'm confident that, if you're a doctor, that one of the best ways to get a detailer into your office would be if you switched to prescribing a generic drug over a brand drug.

Also testifying in favor of the legislation was the president-elect of the New Hampshire

³³ An earlier, less comprehensive hearing was held before the House Committee on Health, Human Services and the Environment.

Medical Society, Dr. Seddon Savage, who said the law "will deter marketing intended to manipulate the practice of individual physicians that is intended to increase market share for the individual companies, possibly at the expense of appropriate decision making for the patients." He further stated that "[n]umerous studies have shown that . . . [doctors'] decision making can be and sometimes is shaped by marketing efforts."

Savage's general testimony was reinforced by comments from Dr. Marc Sadowsky, a psychiatrist and the president of the New Hampshire Medical Society. He reported a phone conversation with a patient who said that her primary care doctor had thought a brand-name medicine might be better for her than the generic she was using. Sadowsky continued:

I said, "Well, you're doing fine on the generic and your co-pay is going to go up \$40 a month, \$500 a year. So, it is not entirely clear to me why we're doing this." . . . I think that that was an example of the primary care physician having been marketed to directly and didn't really have a clinical reason for doing it except that that was the last drug rep who came to see him and said this is a better medicine for anxiety, even though the person was asymptomatic at the time.

In Sadowsky's view, there was "no apparent reason" for the requested switch "except presumably that [the doctor] ha[d] been marketed to effectively."

Among those speaking against the statute was a representative of the New Hampshire Association of Chain Drug Stores, Stuart Trachy, who described the proposed legislation as "too broad" and observed that "the opt out program that the AMA is going to be instituting should take care of the concerns that we have heard in terms of specific doctors being concerned that their prescribing data is out there." A spokesman for plaintiff IMS, Robert Hunkler, stated that restricting prescriber-identifiable information would not lower health care costs because "pharmaceutical companies will[] in all likelihood continue to send sales reps to all doctors without the ability to more specifically hone in on the right people with the right message. It will likely incur more costs to the system." Hunkler also predicted that the acknowledged beneficial uses of the data, including medical research, would be compromised because the information would no longer be readily available. Responding to complaints from doctors that drug companies "know more about [their] prescribing behavior than [they] know," Hunkler stated that IMS was working toward greater access: "[W]e think that a preferable solution is to provide this information to doctors, to health researchers and others instead of turning out the light and taking it away from everyone." The American Medical Association also expressed opposition to the legislation, commenting in a prepared statement that the PDRP would "provide[] physicians with the tools they need to restrict information that they do not want shared while avoiding

legislatively-mandated restrictions that could have unintended consequences.”

2. Legislative Action and Legal Challenge

The Prescription Act was approved by the Legislature in May 2006, and it took effect on June 30 of that year. Four weeks later, on July 28, 2006, IMS and Verispan filed the complaint in this case, alleging that the Act violated the First Amendment and the Commerce Clause, and that it was void for vagueness and overbreadth. They sought declaratory and injunctive relief against the statute’s enforcement. Meanwhile, in compliance with the Act, Verispan modified its databases so that it could identify and suppress all prescriber-identifiable data from New Hampshire prescriptions before the information was released to third parties. IMS also stopped selling prescriber-identifiable information obtained from New Hampshire sources to third parties.

During a four-day bench trial in January and February 2007, the court heard live testimony from ten witnesses, most of whom were physicians. A former detailer and a representative of each plaintiff also testified. The parties also submitted voluminous written materials, including a number of journal articles describing studies on detailing. The State highlighted the testimony of Dr. Jerry Avorn, a professor at Harvard Medical School whose research focuses on the use of prescription drugs and their outcomes, and who also works at Brigham and

Women's Hospital in the Division of Pharmacoepidemiology and Pharmacoeconomics.³⁴ Through Avorn's testimony on the medical literature and the testimony of practitioners who recounted specific experiences with detailing, the Attorney General sought to show that detailing in general, and use of prescriber-identifiable data in particular, influences physicians to prescribe brand-name drugs more frequently than would occur with "evidence-based" decision-making that was untainted by the detailers' marketing messages.³⁵ The Attorney General asserted that the Act advanced the State's substantial interests in prescriber privacy, public health and cost-containment.

On their behalf, the plaintiffs elicited considerable testimony about the beneficial aspects of detailing and the use of prescriber-identifiable data to

³⁴ He explained those two fields as follows:

Pharmacoepidemiology is the study of the utilization of drugs in large populations, as well as the consequences of that use, whether a benefit or adverse event; and pharmacoeconomics is the connection between drug use and economics, what the drugs cost[], but also how they fit into the health care system and what their benefits might save the health care system.

³⁵ The parties and witnesses at times contrasted prescribing decisions that relied on "evidence-based" data - i.e., decisions resulting solely from consideration of replicable clinical data - with decisions influenced by the "contact and communication" from detailers. See, e.g., Stipulation of Facts, at 12; Avorn and Kesselheim Declaration, at 5; Avorn Testimony, Day 3, PM Session, at 60, 110.

target physicians. For example, Dr. Thomas Wharton, Jr., director of cardiology at Exeter Hospital, testified that discussions initiated by drug company representatives provide "a very stimulating forum" for discussing the treatment of coronary disease.³⁶ He also stated that the "level of discourse is elevated" when a drug representative knows his prescribing habits: "[I]f they know that I'm a user of the drug, they will direct what they have to say to me toward any brand-new information that might have come out rather than starting with the basics. If they know that I'm a user of a drug, I would think that they are more likely to come to me if a new adverse effect is announced regarding that drug." Plaintiffs also emphasized the lack of evidence showing that restriction of prescriber-identifiable data would lead to a decrease in drug costs and attempted to show that less efficient detailing would result, potentially increasing the pharmaceutical companies' marketing costs and, in turn, increasing the cost of their products.³⁷

³⁶ Wharton stated that "there is a lot of good intellectual stimulation, education, cross-fertilization, all in a sense based upon the drug rep initiating discussion, presenting data, presenting papers, some of which we know about and some of which we don't. So it's a very educational, informational experience."

³⁷ Plaintiffs offered two anecdotes on this point through Dr. Wharton. First, he testified that, since passage of the Prescription Act, he had been "visited for the first time ever" by a detailer seeking to sell drugs for diabetes, a condition his practice does not treat. In addition, Wharton stated that he was surprised that it took "months and months and even a request to the company" for him to be detailed on a "purportedly

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C. The District Court's Decision

On April 30, 2007, the district court ruled that the Prescription Act impermissibly restricted commercial speech and therefore violated the First Amendment. It rejected the Attorney General's argument that the Act targeted only unprotected factual information rather than constitutionally protected speech and also rejected her contention that the statute regulated only non-speech "uses" of the prescriber-identifiable data. Having concluded that the Act restricted protected commercial speech, the court examined whether the Attorney General had sufficiently justified the regulation under the three-part inquiry set out in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980).

Under *Central Hudson*, truthful commercial speech that does not promote unlawful activity may be limited only if it "(1) is in support of a substantial government interest, (2) 'directly advances the governmental interest asserted,' and (3) 'is not more extensive than is necessary to serve that interest.'" *El Dia, Inc. v. P.R. Dep't of Consumer Affairs*, 413 F.3d 110, 113 (1st Cir.2005) (quoting *Central Hudson*, 447 U.S. at 566, 100 S.Ct. 2343). The district court considered the State's asserted interests in protecting prescriber privacy, promoting public health, and

revolutionary" anti-smoking drug, despite the practice's substantial history of prescribing other anti-smoking products.

containing health care costs. It concluded that the record did not reveal a distinct privacy interest that was supported by the Act and held that neither the public health interest nor the interest in containing health care costs was directly advanced by the statute.

In addition, the court found a "fundamental flaw" in the Attorney General's argument that the regulation was necessary because "pharmaceutical companies manipulate health care providers by using prescriber-identifiable data to enhance the effectiveness of highly persuasive but truthful commercial speech." 490 F.Supp.2d at 181. Instead of restricting such information, the court stated, "if the State is concerned that truthful detailing is causing health care providers to make inadvisable prescribing decisions, 'the remedy to be applied is more speech, not enforced silence.'" *Id.* (quoting *Whitney v. California*, 274 U.S. 357, 377, 47 S.Ct. 641, 71 L.Ed. 1095 (1927) (Brandeis, J., concurring)).

The court also addressed the third *Central Hudson* prong and found that the State could advance its health and cost-containment interests, and specifically the unnecessary prescription of brand-name drugs, without restricting protected speech. The court noted that the State could, inter alia, directly limit the samples and gifts given to prescribers and their staffs, educate health care providers about the health and cost implications of their prescribing decisions, require health care providers to participate in continuing education programs offering objective

information about the advantages and disadvantages of different drug choices, or adopt a Medicaid pharmacy program that takes cost considerations into account.

Accordingly, the court held that the statute could not be enforced "to the extent that it purports to restrict the transfer or use of prescriber-identifiable data." *Id.* at 183. It therefore granted the plaintiffs' request for declaratory relief and a permanent injunction. It did not reach their vagueness or Commerce Clause arguments.

III.

The Attorney General continues to argue on appeal that the Prescription Act restricts only the *use* of information and that this regulation of non-expressive conduct does not implicate the First Amendment. From the Attorney General's perspective, the statute regulates a commercial transaction and not protected speech. *See generally* Neil M. Richards, *Reconciling Data Privacy and the First Amendment*, 52 UCLA L.Rev. 1149, 1194 (2005) (concluding that restrictions on use of consumer data to target advertisements were "not a regulation of speech at all, but rather a regulation of information use – the business activity of deciding to whom to market products"). At trial, the Attorney General contended that the Act did not restrict the content of the pharmaceutical manufacturers' advertising or marketing messages, which she acknowledges would

trigger First Amendment scrutiny.³⁸ Rather, the legislature made the "unusual" – and in the Attorney General's view – permissible choice "to strike at the source of the information," Day 1, AM Session, at 45, thereby regulating the distribution and use of a "commodity" rather than limiting a speaker's message.³⁹

Like the district court, I think this argument attempts to create a dividing line that does not exist in the factual context of this case. While the statute

³⁸ The Attorney General points out that the Act does not regulate the "speakers" (the pharmaceutical companies) at all, but restricts only the entities that sell prescriber-identifiable prescription data to other parties.

³⁹ The Attorney General wisely no longer contends that the First Amendment is inapplicable to the Prescription Act because it targets only factual information. As the district court held, "the transmission of truthful information concerning the prescribing practices of New Hampshire's health care providers . . . is not exempt from First Amendment review merely because it targets factual information rather than viewpoints, beliefs, emotions, or other types of expression." 490 F.Supp.2d at 175; see *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 762, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976) ("Purely factual matter of public interest may claim protection."); *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446-47 (2d Cir.2001) ("Even dry information, devoid of advocacy, political relevance, or artistic expression, has been accorded First Amendment protection.") (citing Supreme Court precedent). Moreover, while the statute directly regulates the prescriber-identifiable data, the Legislature's objective is to restrict the messages presented by the detailers to their physician customers. As I explain, this objective informs my assessment of the regulation.

explicitly prohibits any "use" of prescriber-identifiable data,⁴⁰ one of the Legislature's desired outcomes is the modification of the marketing messages communicated by pharmaceutical detailers. *See, e.g.*, Defendant's Memorandum of Law in Support of its Objection to Plaintiff's Motion for Preliminary Injunction, at 30-31 ("By prohibiting the license, transfer, use, or sale of prescriber-identifiable prescription data for commercial purposes, the Act prevents pharmaceutical companies from using that information to pressure physicians into changing their prescriptions from less costly medications to name brand drugs for reasons unrelated to the clinical needs of patients."). The State has attempted to insulate this expression-based intention from First Amendment scrutiny by directing its legislation to an earlier step in the communicative process. However, it may not skirt the Constitution's requirements in such fashion. Indeed, the Attorney General seeks to minimize the impact of the Act by emphasizing that detailers may continue to use the same face-to-face marketing approach with physicians, notwithstanding the Prescription Act. But if the State acknowledges that the form of marketing conduct remains the same (i.e., face-to-face promotion by detailers), it is difficult to see how the statute may be viewed solely as a regulation of the commercial transaction itself, rather than

⁴⁰ In addition to the catch-all prohibition on "use," the statute, as previously noted, prohibits the licensing, transfer or sale of the information.

as a limitation on the content of the expression that may be used to conduct that transaction. See *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232 (10th Cir.1999) (finding that prohibition of telecommunications companies' use of customer proprietary data for targeted marketing constitutes a restriction on protected commercial speech).

I recognize that there are three separate commercial activities involved here: first, the transfer of the data to data miners, including the plaintiffs, from the entities that acquire prescription information in the ordinary course of their businesses (such as pharmacies and insurance companies); second, the transfer of the data in aggregated form from the plaintiffs to the pharmaceutical companies; and, third, the marketing of drugs to prescribers by detailers whose sales pitches make use of the data. To serve its interests in protecting privacy, promoting public health and containing health care costs, the Legislature targeted the content of the message communicated in the third transaction. The statute restricts that message indirectly by imposing restrictions on the first two transactions.⁴¹ Because the statute's

⁴¹ The Prescription Act expressly governs the first type of transaction by restricting the conduct of "any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity." Whether the Legislature viewed the plaintiffs – the "middlemen" in the data transfer process – as "electronic transmission intermediar[ies]" or "other similar entit[ies]" is unclear, but I think they are properly treated as such for purposes of our

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purposes are linked to the third transaction, I conclude – as did the district court – that the assessment of the statute's impact must be similarly focused.⁴² See *IMS Health*, 490 F.Supp.2d at 176 (“The law is . . . squarely aimed at speech that proposes a commercial transaction even though it does not explicitly bar such speech.”); *Boos v. Barry*, 485 U.S. 312, 321, 108 S.Ct. 1157, 99 L.Ed.2d 333 (1988) (noting that “[r]egulations that focus on the direct impact of speech on its audience” must be viewed as speech-based for purposes of First Amendment analysis).

The Attorney General asserts that the Supreme Court drew “a sharp distinction” in *Bartnicki v. Vopper*, 532 U.S. 514, 121 S.Ct. 1753, 149 L.Ed.2d 787 (2001), between regulating the *use* of information – which she claims does not implicate the First

discussion. To comply with the statute, all parties making this prescriber-identifiable available for sale presumably must condition the sale on an agreement by the purchasers not to use the data in ways prohibited by the Act. By restricting the release of the information into the marketplace, the State limits the content of the message ultimately communicated by the detailers.

⁴² The State's interest in patient privacy is implicated as well by the first two transactions, through which prescription data is transferred to entities uninvolved in individual patients' health care. That interest does not play a part in our analysis because, as noted, the plaintiffs do not challenge the statute's restriction on patient-identifiable data. The State's articulated privacy interest in prescriber information is intertwined with its health and cost-containment interests and relates solely to the third transaction. See *infra* Section IV.A.

Amendment – and regulating its *disclosure*. In *Bartnicki*, the Court held that the First Amendment protected a reporter's disclosure of the contents of an illegally intercepted communication about a matter of public interest. *Id.* at 518, 121 S.Ct. 1753. In its discussion, the Court described a prohibition against the "use" of the contents of an illegal wiretap as "a regulation of conduct," while holding that a prohibition against the "disclosure" of such material "is fairly characterized as a regulation of pure speech." *Id.* at 526-27, 121 S.Ct. 1753. The Attorney General seizes on this language to argue that the Prescription Act and its prohibition against "use" of prescriber-identifiable data is similarly immune from First Amendment attack. However, the examples of prohibited "uses" listed by the Court in *Bartnicki* are materially different from the prohibition at issue here. They involve conduct in which the impact on speech is non-existent or, at most, incidental – for example, using unlawfully intercepted information about a business rival to create a competing product or using illegally recorded information to trade in securities or for extortion. *Id.* at 527 n. 10, 121 S.Ct. 1753. Here, by contrast, the prohibited "use" at issue is the dissemination of a commercial message through marketing, advertising or promotion – expressions that unquestionably are entitled to First Amendment protection. See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 366-67, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002) (quoting *Va. State Bd. of Pharmacy*, 425 U.S. at 763, 96 S.Ct. 1817, for the proposition "that a 'particular consumer's interest in the free flow of

commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate'").⁴³

The multi-step nature of the statutory prohibition – imposing the restraint on the providers of the underlying information rather than directly on the communicator of the message – does not remove that protection. Supreme Court precedent establishes that where the goal of a regulation relates to suppression of expression, even a restriction that indirectly achieves that objective may run afoul of the First Amendment. See *Grosjean v. Am. Press Co.*, 297 U.S. 233, 249, 56 S.Ct. 444, 80 L.Ed. 660 (1936) (invalidating a license tax on publications with circulations of 20,000 or more that sold advertising “because, in light of its history and of its present setting, it is seen to be a deliberate and calculated device in the guise of a tax to limit the circulation of information to which the public is entitled”); see generally *Minneapolis Star & Tribune Co. v. Minnesota Comm’r of Revenue*, 460 U.S. 575, 581, 103 S.Ct. 1365, 75 L.Ed.2d 295 (1983)

⁴³ The Attorney General’s analogy to *Bartnicki* is not entirely inapplicable to the Prescription Act. The prohibited commercial purposes listed by the Act also include “evaluat[ing] the prescribing behavior of an individual health care professional . . . or the effectiveness of a professional pharmaceutical detailing sales force.” Such activities do not themselves constitute protected commercial speech and are equivalent to the “uses” identified in *Bartnicki*. They are not our concern here.

(holding unconstitutional a tax on newsprint and ink used in the production of newspapers).⁴⁴

By contrast, legislation whose purpose is to regulate economic conduct, and which only incidentally affects speech, typically does not raise First Amendment concerns. See generally *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 62, 126 S.Ct. 1297, 164 L.Ed.2d 156 (2006) ("FAIR") ("[I]t has never been deemed an abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.") (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502, 69 S.Ct. 684, 93 L.Ed. 834 (1949)). Our circuit considered this principle at some length in two related decisions concerning a Rhode Island statute regulating the retail sale of alcohol. See *Wine & Spirits Retailers, Inc. v. Rhode Island*, 481 F.3d 1, 6-7 (1st Cir.2007) ("Wine & Spirits II"); *Wine & Spirits Retailers, Inc. v. Rhode Island*, 418 F.3d 36, 48-49 (1st Cir.2005) ("Wine & Spirits I"). Although the State relies on the *Wine & Spirits* decisions in arguing that the Prescription Act falls outside the First

⁴⁴ The Court in *Minneapolis Star & Tribune Co.* made no finding on the State's motive, but observed that "differential treatment, unless justified by some special characteristic of the press, suggests that the goal of the regulation is not unrelated to suppression of expression, and such a goal is presumptively unconstitutional." 460 U.S. at 585, 103 S.Ct. 1365.

Amendment's scope, those cases support a contrary conclusion.

The regulation at issue in *Wine & Spirits* originally prohibited any "chain store organization" from holding a Class A retail liquor license, but gave the Department of Business Regulation the discretion to determine whether a business was a "chain store." Some businesses were evading the restriction by adopting chain-store-like features within a different business structure, described as "franchised package stores." The State responded by amending the statute to identify the specific conduct it sought to prohibit; i.e., it defined the term "chain store organization" to include businesses that participated in "a coordinated or common advertisement with one or more liquor licensed business in any advertising media" or that coordinated marketing strategies. At the same time, the State adopted a provision explicitly excluding franchisees from holding Class A liquor licenses.⁴⁵ *Wine & Spirits* had been operating as a franchisor of independently owned liquor retailers and, among other activities, provided marketing, advertising and

⁴⁵ The statute provides, in part:

To promote the effective and reasonable control and regulation of the Rhode Island alcoholic beverage industry and to help the consumer by protecting their choices and ensuring equitable pricing. Class A liquor license[s] authorized by this title shall not be granted, issued, renewed or transferred to or for the use of any liquor franchisor or franchisee.

R.I. Gen. Laws § 3-5-11.1(a).

business advice and services. In the first of the two cases, *Wine & Spirits* claimed that the regulation improperly infringed on its right to communicate with its customers by, for example, designing advertisements and arranging for their placement in various media. *Wine & Spirits I*, 418 F.3d at 49. In the second case, we also considered a claim by *Wine & Spirits'* franchisees that the regulation imposed an improper limitation on the content of their advertising. *Wine & Spirits II*, 481 F.3d at 6.

We found no First Amendment issue in either instance. In the first case, we stated that the regulation did not "prohibit the communication of advice between a franchisor and the holders of Class A liquor licenses," 418 F.3d at 47, but only forbade implementation of *Wine & Spirits'* business model. We concluded that "[t]he provision of advertising and licensing services is not speech that proposes a commercial transaction and therefore does not constitute commercial speech." *Id.* at 49. In the later case, we observed that the prohibition on coordinated or common advertisements "does not target speech; each individual liquor licensee remains at liberty to disseminate information about its prices and products to other retail stores and to the public at large." 481 F.3d at 6. We observed: "The statute at issue here merely proscribes conduct – the launching of advertisements resulting from pre-agreed commercial strategies. Such a ban is not a ban on commercial speech." *Id.*

Thus, the *Wine & Spirits* prohibition was against an acting-in-concert business approach – not against the message the liquor stores were seeking to disseminate.⁴⁶ To be sure, the statute had an incidental impact on the speech of both the franchisor and franchisees. *Wine & Spirits* was, in effect, prevented from marketing its services to particular businesses, and the franchisees could not distribute advertisements in coordination with other retail liquor stores. But the statute's objective was to regulate business methods, see *supra* n. 35, and, as we observed in *Wine & Spirits I*, "the First Amendment does not safeguard against changes in commercial regulation that render previously profitable information valueless." 418 F.3d at 48.

Here, however, the Legislature did not simply prohibit a business model or strategy. Instead, it restricted the substance of the messages being communicated by pharmaceutical detailers in their sales pitches by curtailing information previously available to detailers. In other words, the State targeted, albeit indirectly, the speech of the detailers in order to achieve its multiple objectives. Such a regulation is a limitation on commercial speech, and the State consequently must bear the burden of demonstrating that it satisfies the *Central Hudson* test. See, e.g., 44

⁴⁶ We observed that "the statute imposes no burden on the communication between the speaker and the intended audience but has the effect of decreasing the audience's demand for a particular kind of business advice." 418 F.3d at 48 n. 3.

Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 499, 116 S.Ct. 1495, 134 L.Ed.2d 711 (1996) (noting that “the State retains less regulatory authority when its commercial speech restrictions strike at ‘the substance of the information communicated’ rather than the ‘commercial aspect of [it]’”) (quoting *Linmark Assocs., Inc. v. Willingboro*, 431 U.S. 85, 96, 97 S.Ct. 1614, 52 L.Ed.2d 155 (1977)); cf. *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 429, 113 S.Ct. 1505, 123 L.Ed.2d 99 (1993) (noting the Court’s prior “statements that the test for whether a regulation is content based turns on the ‘justification’ for the regulation”) (citing *Ward v. Rock Against Racism*, 491 U.S. 781, 791, 109 S.Ct. 2746, 105 L.Ed.2d 661 (1989); *Clark v. Cmty. for Creative Non-Violence*, 468 U.S. 288, 293, 104 S.Ct. 3065, 82 L.Ed.2d 221 (1984)).⁴⁷

⁴⁷ The plaintiffs argue that the Act should be analyzed as a content-based restriction on speech subject to strict scrutiny rather than as a regulation of commercial speech subject to intermediate scrutiny. Although the statute unquestionably affects content by limiting the information the detailer may communicate, I find no merit in this view of the applicable standard. The targeted speech concerns the promotion of a product – the classic context for commercial speech. Content-based restrictions on commercial speech are subject only to intermediate scrutiny. See *Naser Jewelers, Inc. v. Concord*, 513 F.3d 27, 33 (1st Cir.2008) (“*Central Hudson* serves as an alternative to the more exacting standards applied to content-based restrictions on non-commercial speech.”). Alternatively, the plaintiffs contend that the statute should be subject to strict scrutiny because it has a chilling effect on non-commercial speech. However, I agree with the majority that, properly

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IV.

Before delving into the *Central Hudson* test and its application here, I pause briefly to clarify what this case is not about. We are not considering the State's authority to restrain untruthful, unlawful or otherwise misleading speech. Such communications – e.g., insider information about securities, fraudulent statements, or speech that would violate intellectual property laws – are routinely regulated without First Amendment inquiry.⁴⁸ Although the State is concerned about the potentially misleading effect of the information provided by detailers to prescribers, it does not characterize the messages it seeks to restrict as categorically untruthful or deceptive. Thus, my analysis presumes that New Hampshire's prohibition on the use of prescriber-identifiable data affects communications that are truthful and otherwise lawful. As such, they may be limited only with adequate justification.

To justify a commercial speech restriction, the State bears the burden of proving the three elements

construed, the terms of the statute are exceedingly narrow and that, so understood, the Act does not impermissibly burden speech outside its scope.

⁴⁸ The Supreme Court has treated as a threshold question under the *Central Hudson* test "whether the commercial speech concerns unlawful activity or is misleading." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002). "If so, then the speech is not protected by the First Amendment." *Id.* My references to the three-pronged *Central Hudson* inquiry do not include this preliminary inquiry.

of the *Central Hudson* test: (1) the restriction is in support of a substantial government interest; (2) it directly advances the asserted interest; and (3) it is "not more extensive than is necessary to serve that interest." *Central Hudson*, 447 U.S. at 566, 100 S.Ct. 2343; *El Dia*, 413 F.3d at 113; see also *Thompson*, 535 U.S. at 367, 122 S.Ct. 1497. I consider each prong in turn.

A. Substantial Government Interest

The Attorney General maintains that the Prescription Act supports the State's substantial interests in protecting patient and prescriber privacy, promoting public health, and containing health care costs. Although the plaintiffs do not challenge the importance of the public health and cost-containment interests, they contend that the evidence in the record fails to prove that either interest is directly advanced by the statute as required by the second prong of *Central Hudson*. They wholly reject the Attorney General's contention that the Act serves a privacy interest.

I, too, accept as substantial the State's asserted interests in cost-containment and quality health care. However, I join the district court in rejecting on this record prescriber privacy as a sufficient interest to justify the Prescription Act. The State does not claim an interest in preventing public disclosure of the prescriber-identifiable data, and indeed it could not, as the statute allows the data to be disclosed and

used for a myriad of purposes. See Defendant's Trial Memorandum, at 20 n. 10 (conceding that the law does not "attempt to keep prescriber-identifiable data secret or entirely private").

Rather, the Attorney General explains in her brief that the State's privacy interest is in the "patient-physician relationship," specifically in New Hampshire patients' "reasonable right to expect that their relationship with the physician is private, and [that] a pharmaceutical detailer is not manipulating the physician's prescribing behavior." The Attorney General contends that detailers have become "an invisible intruder in the physician's examination room."

However, the regulation does not in any cognizable way touch on the privacy of the examination room. Although the statute bars disclosure of patient-identifiable information as well as prescriber data, the plaintiffs do not challenge the prohibition on the use of specific patient data. Thus, no patient identifying information is at issue in this case. Any privacy justification must therefore reside in the *prescriber-identifiable* data. Rather than arguing that "the [prescriber-identifiable] data is being exploited to compromise patient privacy," the Attorney General argues that "pharmaceutical companies are using the data to help persuade doctors to make inadvisable prescribing decisions." 490 F.Supp.2d at 179. The district court properly recognized the flaw in this depiction of a privacy interest:

[W]hat the Attorney General claims as a distinct interest in protecting prescriber privacy is nothing more than a restatement of her contentions that the law can be justified because it prevents pharmaceutical companies from using prescriber-identifiable data in ways that undermine public health and increase health care costs.

Id. Accordingly, I join the district court in rejecting the Attorney General's argument that the Prescription Act is justified by a substantial privacy interest.

I thus turn to consider whether the Prescription Act is a narrowly tailored provision that directly advances the State's substantial interests in quality health care and cost-containment.

B. Advancing the Interest

The Attorney General asserts that the Prescription Act satisfies the second prong of the *Central Hudson* test – that it advances the State's interest – because it reduces the likelihood that prescribers will make unnecessarily expensive and unwise drug choices. I borrow the district court's well stated description of the Attorney General's logic:

The chain of reasoning . . . begins with the major premise that prescriber-identifiable data allows pharmaceutical companies to target health care providers for marketing and tailor marketing messages in ways that make detailing more persuasive. Next, it assumes that because prescriber-identifiable

data makes detailing more persuasive, it inevitably leads to more prescriptions for brand-name drugs when compared with generic alternatives because only branded drugs are detailed. Finally, it assumes that any increase in the number of prescriptions written for brand-name drugs when compared to generic alternatives harms the public health and increases health care costs because branded drugs often turn out to be more harmful than generic alternatives and almost always are more expensive. Accordingly, a ban on the use of prescriber-identifiable data for marketing purposes promotes public health and contains health care costs by prohibiting pharmaceutical companies from using prescriber-identifiable data to promote the sale of brand-name drugs.

490 F.Supp.2d at 180.

The district court accepted the premise that detailing with prescriber-identifiable data is more persuasive, but found that the Attorney General had failed to establish a link between such detailing and any negative impact on public health or drug costs. On the health concern, the court found that it is "counterintuitive and unproven" that, on balance, "brand-name drugs are more injurious to the public health than generic alternatives." *Id.* In addition, the court was unpersuaded that the State's public health purpose was served by barring the use of prescriber data to target "early adopters" of new drugs because

"the record does not establish either that early adopters are more likely to be influenced by detailing than other health care providers or that new drugs are generally more injurious to the public health than existing medications." *Id.*

The court found the Attorney General's position on cost-containment similarly deficient. It stated that "[n]on-bioequivalent generic drugs are not always as effective as brand-name alternatives," *id.*, and found that the Attorney General had not proven that any reductions in health care costs stemming from reduced use of newer, more expensive medications "can be achieved without compromising patient care." *Id.* at 181. It thus found that none of the State's asserted interests was advanced by the Prescription Act. Moreover, to the extent that the Attorney General successfully drew a connection between truthful, non-misleading detailing based on prescriber-identifiable data and "inadvisable prescribing decisions," the district court opined that more speech, not less, was the remedy required by the First Amendment. *Id.*

I consider the State's showing on each of the two interests in turn.

1. Interest in the Quality of Health Care

To validate the Prescription Act on the basis of its impact on the quality of health care, the Attorney General needed to show that detailing with prescriber-identifiable data influences medical professionals to choose drugs that are less safe or less

appropriate to meet patients' needs than the non-patented alternatives they would otherwise prescribe. I agree with the district court that no evidence in the record supports the proposition that newer, brand-name drugs are generally less safe or effective than older, generic ones.

The record does contain evidence that, at times, physicians are persuaded to prescribe new drugs that are less effective for patients. Dr. Avorn testified that, in the wake of extensive marketing for new hypertension medications, known as calcium-channel blockers, many doctors switched from "better, older, less-marketed products" to new products that gave patients "less benefits in terms of preventing strokes or heart disease." The record did not, however, support a conclusion that such occurrences were the norm; rather, the Attorney General's evidence primarily was directed toward showing that detailing routinely persuades health care professionals to prescribe patented medications when they offer no benefit over cheaper generic alternatives. In other words, the Attorney General's focus was on the unnecessarily high prices paid for functionally *equivalent* drugs. That circumstance is pertinent to the cost-containment interest I discuss in the next section, rather than to an interest in safe and appropriate health care.

Other evidence relevant to the interest in quality health care showed that detailers use prescriber-identifiable data to target early adopters, who then prescribe promoted new drugs that sometimes turn out to have harmful side effects. However, the

Attorney General's argument is not that a greater number of physicians become early adopters *because of* targeted detailing; it claims the pharmaceutical companies use the data to identify physicians who already are inclined to adopt new drugs. In other words, the targeted doctors would likely have been among the first users of new drugs in any event. Thus, the possible adverse effect on health care stemming from reliance on the prohibited data would arise only from the possible difference in time between an early adopter's alert from a detailer and the physician's notice from another source. The record provides no basis for concluding that, in the ordinary case, that difference in time would have a significant health effect.⁴⁹

However, the evidence *did* indicate that access to early adopters was economically advantageous for the pharmaceutical companies. By soliciting the earliest possible use of new medications, the companies can maximize the financial advantage of their exclusive rights while their high-priced drugs are patent-protected. See, e.g., Day 3, PM Session, at 52

⁴⁹ It is worth noting that *some* patients inevitably must be exposed to the risks of trying new drugs because it is through use by patients, after more limited clinical testing, that side effects and other problems are detected. In addition, the risks must be weighed against the benefits of early adoption of drugs that prove to be "breakthrough" developments in treatment. See, e.g., Day 4, AM Session, at 100 (Testimony of Randolph Frankel); AM Session (Part 2), at 15 (recording State counsel's observation that "obviously sometimes a newer drug is better").

(Testimony of Dr. Avorn) (“[The drug companies] are very conscious that the patent life is ticking away, and there’s a tremendous impetus on the part of the industry to be able to maximize their income as much as possible the minute the drug is released on the market.”). While a few weeks or months delay in adoption of a new drug might make a substantial financial difference, the Attorney General has not shown that it would have material health consequences.

It is unsurprising that I find the Attorney General’s showing on the State’s health care interest to be inadequate – or at least undeveloped – given that justification’s limited role in both the legislative process and the trial. Promoting quality health care was not one of the two purposes of the law identified by the Act’s sponsor when she introduced the legislation,⁵⁰ and the district court noted that the legislative history contained no “substantial support for the view that it was promoted as a public health measure, except to the extent that containing healthcare costs itself has a positive public health benefit.” Tr. of Status Conference, April 11, 2006, at 44.⁵¹ In a

⁵⁰ In addition to Representative Rosenwald’s statement about the purposes of the Act, the co-sponsor, Senator Foster, stated during the Senate Floor Debate that “[t]o me what this legislation is about is dollars and cents.”

⁵¹ In reviewing the State’s interests during a mid-trial oral hearing, the district court stated: “I didn’t see any discussion in the legislative history that . . . targeted detailing was leading to unhealthy prescription practices; that doctors were injuring

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colloquy with counsel toward the end of the trial, the court observed that it did not see "one shred of evidence in this record, either in the legislative history or in the trial" that prescription of higher-priced drugs instead of generics "produces unhealthy or less healthy outcomes for anybody in New Hampshire." Additionally, the plaintiffs effectively countered the Attorney General's limited showing on adverse health effects with evidence that targeted detailing is just as likely to offer health benefits; it allows drug companies to quickly alert prescribers when new drug side-effects are discovered and provides early notification to specialists of helpful new treatments for their patients.⁵² Thus, I agree with the district court that the record fails to show that the Prescription Act directly advances the State's interest in safer or better medical care. See *44 Liquormart*, 517 U.S. at 505, 116 S.Ct. 1495 ("[A] commercial speech regulation 'may not be sustained if it provides only

their patients by denying them therapies that they would benefit from or by giving them drugs that would harm them. . . . This is a bill about costs. It's not a bill about safety." Day 4, AM Session (Part 2), at 3-4.

⁵² In his declaration, Randolph B. Frankel, vice president of public affairs at IMS, stated that early adopters' delayed awareness of innovative drugs affects patients other than their own because other prescribers deliberately wait for early adopters to test the safety and effectiveness of the drugs. He commented: "When new drugs that have been tested and approved are not adopted or adopted very slowly this generally harms public health and may increase the overall cost of public healthcare." Declaration, at 10.

ineffective or remote support for the government's purpose.'") (quoting *Central Hudson*, 447 U.S. at 564, 100 S.Ct. 2343).

2. Interest in Containing Prescription Drug Costs

To justify the statute as a cost-control measure, the Attorney General has the burden of demonstrating that prescriber-identifiable data plays a significant role in the decisions of health care professionals to choose more expensive brand-name drugs over comparably effective, but less expensive, generic alternatives. See 44 *Liquormart*, 517 U.S. at 505, 116 S.Ct. 1495 ("[T]he State bears the burden of showing not merely that its regulation will advance its interest, but also that it will do so 'to a material degree.'") (quoting *Edenfield v. Fane*, 507 U.S. 761, 771, 113 S.Ct. 1792, 123 L.Ed.2d 543 (1993)). In other words, the Attorney General must show that (1) detailing generally has a persuasive effect on physicians and that (2) the use of prescriber-identifiable data magnifies that persuasive effect, increasing the physicians' tendency to prescribe unnecessary brand-name drugs.⁵³

⁵³ I note that targeted detailing is used not only to promote patented, brand-name drugs over generic medicines, but also to encourage prescribers to choose a particular brand-name drug over a patented competitor. The latter situation is not the State's primary concern because the cost difference between brand-name drugs is less likely to be substantial. The State

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a. *The evidence*

The impact of detailing on prescriber drug choice was amply documented by both empirical and anecdotal evidence. The following is a sampling of the evidence submitted to the legislature or at trial:

- Dr. Savage, president-elect of the New Hampshire Medical Society, testified at the Senate committee hearing that “[n]umerous studies” have shown that doctors’ prescribing decisions “can be and sometimes [are] shaped by marketing efforts.”
- During the trial, Savage’s predecessor as president of the medical association, Dr. Sadowsky, related a particular instance when one of his patients, at the suggestion of her primary care doctor, asked for a brand-name drug that Sadowsky considered no better than a less expensive generic. *See supra* Section II.B.1. He attributed the request to detailing of the primary care physician. Sadowsky also testified:

I believe that detailing has had an [e]ffect on my prescribing. I think that just looking back I think that when medicines have gone off patent, I don’t think that I thought about this consciously, but

particularly wants to prevent pharmaceutical sales representatives from unduly influencing physicians and other health care professionals to select more expensive brand-name drugs over considerably cheaper generic options that provide essentially the same benefits.

I think that my rate of prescriptions of those medicines declined in preference to the medicines I was being detailed about.

- The declaration submitted during the trial by Drs. Avorn and Kesselheim reported from their research and others' work that "[p]hysicians use of targeted prescriptions increases substantially after visits with sales representatives," Declaration, at 6, and the same result was reported in an article reviewing academic research on the effect and role of detailing. The article concluded that, "not only is detailing an important source of information, it affects physician prescription behavior in a positive and significant manner." Manchanda & Honka, *supra*, at 787. The article cites multiple studies in which doctors acknowledged that detailing affected their prescribing behavior and reported one study showing that family physicians who relied least on sales representatives were most likely to prescribe generic drugs, "while only 12% of those who said they relied 'a great deal' on detailers prescribed generic drugs." *Id.* at 799.⁵⁴

⁵⁴ Manchanda and Honka also noted that many studies report that physicians believe that prescription behavior may be influenced by detailing.

This opinion is supported by virtually all the studies that have investigated the effect of detailing (either in isolation or with other marketing instruments) using behavioral data either at the market or individual

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- In her article reviewing 29 surveys exploring the relationship between physicians and pharmaceutical sales representatives, Ashley Wazana reported that “[t]here was an independent association between meetings with pharmaceutical representatives and formulary addition requests for the drug of the representative’s company.”⁵⁵ See Wazana, *supra*, at 375. Most of the requested drugs, however, “presented little or no therapeutic advantage over existing formulary drugs.” *Id.*

- A CALPIRG “white paper” contained in the Legislative History cited the finding of a Pennsylvania study that 40% of patients in a state assistance program received hypertension drugs different from those recommended by medical guidelines. According to the paper, the study reported that,

[i]f doctors had prescribed according to those guidelines, the state could have saved \$11.6 million, or nearly 24% of the total money it spent on hypertension medicine. The study suggested that pharmaceutical promotion was partly at

physician level. While there seems to be little consensus about the size of the effect, it is clear that the effect is positive and significant in a statistical sense.

Id. at 809.

⁵⁵ A formulary is a list of drugs approved for use in a particular setting, such as in a hospital or for a Medicaid program.

fault for the variance between the medicines that were recommended versus those that were prescribed.

Emily Clayton, CALPIRG, *'Tis Always the Season for Giving: A white paper on the practice and problems of pharmaceutical detailing* (2004), at 4-5.⁵⁶

The Legislature was thus on solid ground in concluding that pharmaceutical detailing influences prescriber drug choices. The added benefit to pharmaceutical companies of marketing with access to prescriber-identifiable data, although less exhaustively covered, also was the subject of considerable testimony by the Attorney General's witnesses. Their testimony depicted targeted detailing as more aggressive and persuasive, and thus more potent than regular detailing in guiding prescriber behavior toward the detailer's desired outcome – the decision to use the sales representative's patented, brand-name drug. On the specific impact of detailing with prescriber-identifiable information, the evidence included the following:

⁵⁶ Drs. Avorn and Kesselheim also noted the extensive campaigns in favor of new hypertension medications, known as calcium-channel blockers, "despite the fact that professional guidelines did not consider them first-choice therapies for the treatment of hypertension. . . . This distortion of practice away from the use of drugs recommended in national guidelines was estimated to have increased health care expenditures by around \$3 billion dollars [sic] in 1996 alone." Declaration, at 7.

- Dr. Gary Sobelson, a family practice physician, testified at trial that he was unaware of scientific evidence showing that the sale of prescriber-specific data increases drug costs, but observed that such knowledge "puts me at a disadvantage that I'm not comfortable being at." He told of being persuaded to prescribe a brand-name drug, Zithromax, instead of an equivalent generic Amoxicillin, based on an incorrect assumption that Zithromax, which had the advantage of requiring a shorter course of therapy, was minimally more expensive than the older Amoxicillin. After discovering that Zithromax was five times more expensive, he moved away from Zithromax because "I'm interested in prescribing rationally for my patients in a way that both maximizes their outcome but also helps maintain the lowest possible cost to both them individually and, frankly, to our society at large."

- Sobelson also described how detailers use prescriber-identifiable information when marketing to a physician who typically prescribes a competitor's equivalent product, citing two cholesterol-lowering medications, Lipitor and Zocor, in his example:⁵⁷

⁵⁷ The issue here is detailing aimed at promoting a brand-name option over a non-bioequivalent-cheaper-alternative. However, as noted earlier, detailing also is used to influence the choice among competing brand-name drugs. Sobelson's testimony indicating the influence of detailing in the brand-name

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[W]hen a drug representative for Lipitor comes to see me, . . . they are going to know to present data that would focus me to why I should prefer Lipitor over Zocor. It's a very, very specific focus that particularly is fueled if they happen to know that 80 percent of my prescribing is Zocor. And so when the Lipitor rep comes around, they are going to have their targeted information provided by their marketing department. This is how we've learned from our study groups that you get doctors to move from Zocor to Lipitor.

- Sobelson's experience on the receiving end of the marketing dovetailed with the description provided by a former detailer of his strategy when he had prescriber information. Shahram Ahari testified that, when he knew a physician's patterns, "I have a fair idea why, and so it becomes almost a cat and mouse game when I get them to say their objections and for me to shift those objections or doubts and downplay or negate them altogether." By contrast, without prescriber-specific information,

it becomes less about the business and more about knowing the science of my drug. . . . [I]t puts the power of the detail more in the physician's hands because I

setting supports an inference that it is equally effective in the competition between brand-name and generic drugs.

don't truly know what his concerns are or what his perspectives or biases are. . . . [I]t shifts the power of the conversation to a more equal footing.

- A Boston Globe article included in the Legislative History reported similar information; a sales representative told of his understanding that, if he learned that a doctor was prescribing a competitor's product, his presentation should focus on undermining that product. Liz Kowalczyk, *Drug Companies' Secret Reports Outrage Doctors*, Boston Globe, May 25, 2003, at A1.
- Plaintiff IMS has explained the benefits of data-mining with a focus on prescriber-specific data: "By using a data-mining solution, IMS can pinpoint prescribers who are switching from one medication to another. A sales person can use this model to target doctors who have switched from the drug they are selling and to devise a specific message to counter that switching behavior." Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How We Turned a Mountain of Data into a Few Information-rich Molehills*, IMS Abstract.
- In both his testimony and declaration, Dr. Avorn stated that detailing becomes less information-focused and a more powerful tool of persuasion when the sales representative is armed with prescriber-specific information. In his joint declaration with Dr. Kesselheim, he related the "counter-detailing" experience of

his research unit at Harvard Medical School, in which he and his colleagues used prescriber-specific data obtained from pharmacy records to choose physicians for educational visits by clinical pharmacists, accompanied by mailed "unadvertisements." He reported that these targeted interventions resulted in a 14 percent reduction in inappropriate prescriptions,⁵⁸ Declaration at 9, and he saw significance in these results for commercial detailing:

Our educational programs (known as "academic detailing") focused on improving patient care through reducing excessive use of inappropriate medications. But when these techniques are used by companies whose main goal is simply to increase product sales, the impact on patients and on the health care system are quite different. The studies we have cited indicate that more physician-specific detailing will lead to more prescriptions of brand-name agents, often with no additional patient benefit but at much higher cost to patients and to state-based insurance programs, which will continue to drive up the cost of health care in New Hampshire.

Id. at 10.

⁵⁸ As discussed *infra*, the plaintiffs cite this success with counter-detailing as evidence that the State could have achieved its objective of cost-containment without suppressing speech. As I explain, counter-detailing is not a comparable alternative.

Avorn echoed these observations at trial, explaining that prescriber-identified data was important to the success of his counter-detailing because "that's how we knew whom to visit, and we also knew what to say to them because we knew what drugs they were prescribing." In the declaration, he stated that restricting access to prescriber-specific information, "[m]aking it more difficult for manufacturers to tailor their marketing strategies to . . . individual physicians[,] would actually encourage detailers to present physicians with a more neutral description of the product that would emphasize presentation of information over promotion." Declaration, at 11; *see also* Day 3, PM Session, at 140 (Avorn Testimony) ("[I]f the sales rep knows my prescribing history, they will market to me or at me in a way that goes well beyond just providing me with the data. It's not really education at that point. It's not a level playing field.").

- An assumption that prescriber-identifiable detailing impacts drug choice is reflected in the professional guidelines cautioning against using the data aggressively. As noted above, the AMA has adopted suggestive guidelines against the use of "prescribing data to overtly pressure or coerce physicians to prescribe a particular drug." Such indirect evidence supports the State's view that eliminating access to the information will decrease the likelihood that physicians will be swayed by targeted marketing to prescribe unnecessary – and more expensive – brand-name drugs.

b. *The district court's evaluation of the evidence*

The district court concluded that, notwithstanding this evidence, the State's showing was insufficient to establish a link between the Prescription Act and cost-containment because other evidence showed that more expensive brand-name drugs will, at times, be the better therapeutic choice.⁵⁹ The court acknowledged that "substantial deference" must be given to a

⁵⁹ The court explained its reasoning on the cost-containment interest as follows:

I am also unconvinced by the Attorney General's argument that the Prescription Information Law directly promotes the State's interest in containing health care costs. The Attorney General appears to assume that any health care cost savings that will result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care. However, this proposition is far from self-evident. Non-bioequivalent generic drugs are not always as effective as brand-name alternatives. Moreover, even in cases where non-bioequivalent generic drugs will work as well or better than a brand-name alternative for most patients, there may be some patients who will benefit by taking the branded medication. Yet, a ban on the use of prescriber-identifiable data affects both helpful and harmful brand-name prescribing practices in the same way. Because the Attorney General has failed to prove that any reductions in health care costs that may result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care, I am unable to endorse her argument that the Prescription Information Law can be justified as a cost containment measure.

legislature's predictive judgments "[w]hen a quality record establishes that the legislature conducted an extensive investigation, acquired considerable expertise in the regulated area, and incorporated express findings into the approved statute." 490 F.Supp.2d at 177 n. 12 (citing *Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 186, 117 S.Ct. 1174, 137 L.Ed.2d 369 (1997)). However, the court questioned the extent of the Legislature's investigation before adopting the initiative, noting, inter alia, that it acted quickly after the bill was introduced, made no express findings on the need for the legislation, and "cited no evidence as to how effective the restriction might prove to be." 490 F.Supp.2d at 177.

I am mindful that regulations that suppress commercial speech must be carefully evaluated. Nonetheless, the district court held the Attorney General to a higher standard of proof than is required by Supreme Court precedent. While a state legislature "does not have the broad discretion to suppress truthful, nonmisleading information for paternalistic purposes," 44 *Liquormart*, 517 U.S. at 510, 116 S.Ct. 1495, the Court's commercial speech cases "recognize some room for the exercise of legislative judgment." *Id.* at 508, 116 S.Ct. 1495. To earn that deference, the State must offer probative evidence that suppressing speech is essential to achieving its goal. However, a state legislature cannot reasonably be expected to undertake an investigation of the scope conducted by Congress in connection with the federal legislation at issue in *Turner Broadcasting*, the case cited by the

district court, to justify a limited restriction on commercial speech. See *Turner Broad. Sys.*, 520 U.S. at 187, 117 S.Ct. 1174 (noting that the record included "tens of thousands of pages" of materials acquired during three years of Congressional preenactment hearings, as well as additional expert submissions, sworn declarations, testimony, and industry documents).

In *Turner Broadcasting*, the Court observed that, given the exhaustive record, Congress's findings were entitled to "deference in part because the institution is far better equipped than the judiciary to amass and evaluate the vast amounts of data bearing upon legislative questions." 520 U.S. at 195, 117 S.Ct. 1174 (internal quotation marks and citations deleted). Although the contexts are different,⁶⁰ the general principle of legislative deference also is compatible with the Court's commercial speech precedent. The question here, as there, is whether the government is able to support its restriction on speech by "'ad-duc[ing] either empirical support or at least sound reasoning on behalf of its measure[].'" *Turner Broad.*

⁶⁰ *Turner Broadcasting* addressed the "must-carry" provisions of the Cable Television Consumer Protection and Competition Act of 1992. In its first decision in the case, the Court held that the provisions imposed content-neutral restrictions on speech that were subject to intermediate scrutiny. *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 661-62, 114 S.Ct. 2445, 129 L.Ed.2d 497 (1994). In its second decision, the Court concluded that the provisions were consistent with the First Amendment. 520 U.S. at 185, 117 S.Ct. 1174.

Sys., 512 U.S. at 666, 114 S.Ct. 2445 (quoting *Century Commuc'ns Corp. v. FCC*, 835 F.2d 292, 304 (D.C.Cir.1987)); see *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 628, 115 S.Ct. 2371, 132 L.Ed.2d 541 (1995) ("[W]e do not read our case law to require that empirical data come to us accompanied by a surfeit of background information. Indeed, in other First Amendment contexts, we have permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and 'simple common sense.'") (citations omitted). If the government makes the requisite showing, we defer to the legislative judgment to adopt the challenged measure.

The Attorney General has no empirical data showing the extent of the influence of prescriber-specific information on physicians' decision-making; nor can she document how much money the Prescription Act will save the State or consumers. The regulation was the first of its kind in the country, and it had been in effect for less than a year when the district court invalidated it. It is unreasonable in these circumstances to expect the Attorney General to provide extensive quantifiable data that might only become available after the statute has been in place for some time. I have described evidence here that establishes a plausible cause-and-effect relationship between targeted detailing and higher drug prices. What is missing is hard evidence of the global extent

of this relationship. Clearly, it will be important going forward for the State to try to measure the cost-containment effect of its initiative, and it is possible that this ongoing assessment will indicate that the measure is not as effective as the State had hoped.

However, at this juncture, the Attorney General has established a factual basis justifying the initiative. She has adduced significant testimony based on relevant empirical research concerning the impact of detailing generally, supplemented by the personal experience of both prescribers and detailers, strongly indicating that sales pitches based on specific prescribing patterns have a particularly persuasive impact on drug choice. The extent of this empirical and anecdotal evidence, particularly in light of the Act's limited restriction on speech, distinguishes this case from those in which the Supreme Court has found more sweeping bans on commercial speech to be inadequately justified. For example, the Court in *Edenfield* noted the absence of any studies or anecdotal evidence to support a ban on in-person solicitation by accountants. 507 U.S. at 771, 113 S.Ct. 1792. In *Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 108 S.Ct. 1916, 100 L.Ed.2d 475 (1988), which rejected a ban on direct-mail solicitations by lawyers, the State "assembled no evidence attempting to demonstrate any actual harm caused by targeted direct mail," *Florida Bar*, 515 U.S. at 629, 115 S.Ct. 2371. See also *U.S. West, Inc.*, 182 F.3d at 1237 (noting that the government had presented "no evidence" showing

that the harm to either of its two asserted interests "is real").

Moreover, as I have recounted, evidence from multiple sources indicated that the expense of unnecessary brand-name prescribing has in the past ranged into the billions of dollars nationally.⁶¹ This substantial evidence of needless spending, combined with evidence that detailing with prescriber-identifiable data contributes to that outcome, is enough to show that the Prescription Act "targets a concrete, nonspeculative harm," *Florida Bar*, 515 U.S. at 629, 115 S.Ct. 2371, and that the Attorney General has sufficiently demonstrated that the State's interest in cost-containment would be furthered "to a material degree" by the limitation on speech it seeks to achieve through the Prescription Act.⁶² See, e.g.,

⁶¹ In summarizing the need for the legislation, Dr. Avorn testified:

I think the problem we're concerned with – and I think the legislation was designed to address – is that we have this epidemic of over-priced drugs just eating the lunch of the older drugs that are both cheaper and safer; and that's not an opinion. That's simply looking at what's happened in the field of hypertension treatment, what's happened with the anti-platelet drug like Plavix. Now, Plavix is an okay drug, and we recommend it in a number of settings but not for everyone who sometimes feels their legs are heavy, like the commercials say; and Plavix costs 160 times what aspirin costs.

⁶² It is particularly difficult to predict the long-term impact of eliminating targeted detailing from the pharmaceutical sales representative's marketing tools. In a submission to the district

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City of Los Angeles v. Alameda Books, Inc., 535 U.S. 425, 426, 122 S.Ct. 1728, 152 L.Ed.2d 670 (2002) (“[A] municipality may rely on any evidence that is ‘reasonably believed to be relevant’ for demonstrating a connection between speech and a substantial, independent government interest.”); cf. *Turner Broad. Sys.*, 512 U.S. at 666, 114 S.Ct. 2445 (“[T]he obligation to exercise independent judgment when First Amendment rights are implicated is not a license to reweigh the evidence *de novo*, or to replace Congress’ factual predictions with our own. Rather, it is to assure that, in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence.”).

Importantly, the district court made no finding that the Attorney General had failed to establish a

court, amici pointed to one potentially significant byproduct of lowered prescription drug costs. They cited studies showing that consumers, particularly older adults, sometimes forego filling or renewing prescriptions because of their cost, leading to higher long-term health care costs. See AARP Memorandum to Dist. Ct., at 13 (“The consequences of cost-related medication underuse include increased emergency department visits, psychiatric admissions and nursing home admissions, as well as decreased health status.”) (quoting John D. Piette, et al., *Cost Related Medication Underuse Among Chronically Ill Adults: the Treatments People Forego, How Often, and Who is at Risk*, 94 Am. J. Pub. Health 1782 (2004)). Although the extent of such behavior may not be readily determined, such studies support the State’s view that lowered drug costs will favorably impact health care expenditures.

relationship between detailers' use of prescriber-identifiable data and increased health costs.⁶³ Instead, the court concluded that the Attorney General had failed to show that the Act advanced the State's interest because any cost savings might be offset by compromised health care for patients who would in fact benefit from the use of more expensive brand-name drugs.

It does not matter that detailing with prescriber-identifiable data sometimes has positive effects. The Attorney General's evidence indicated that the health care *benefits* of such marketing described by plaintiffs are largely achievable in other ways. News reports, for example, would highlight truly groundbreaking new therapies in a timely way and, indeed, pharmaceutical detailers with knowledge of physicians' medical specialties presumably would not need access to prescribing histories to effectively promote such innovations.⁶⁴ Early adopters could be expected to

⁶³ Indeed, as noted earlier, the court "accept[ed] her major premise that pharmaceutical companies use prescriber-identifiable data to make detailing more persuasive." 490 F.Supp.2d at 180.

⁶⁴ Dr. Sadowsky of the New Hampshire Medical Society expressed the view that alternative means existed for learning about new drugs: "I think that the vast majority of physicians are aware pretty quickly through the literature, through the medical literature about any new miracle drugs." Dr. Sobelson agreed: "I don't think I need a detailer at all to make me aware of [a breakthrough drug]. . . . [Y]ou can read about it in the New York Times, but I also certainly heard about it [a new drug for treating Alzheimer's disease] at conferences, from colleagues, from the sources of information that I really want to hear

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respond quickly with an interest in trying the new medications – effectively identifying themselves to the sales representatives.⁶⁵ In addition, as I already have observed, the statute does not bar drug companies from alerting prescribers to newly discovered problems with their medications. In other words, I see no message or interest of consequence that is foreclosed by the regulation.⁶⁶ *Cf. Thompson*, 535 U.S. at 376, 122 S.Ct. 1497 (noting that “the amount of beneficial speech prohibited by the [statute]” would

about.” *See also* Day 3, PM Session, at 57-58 (testimony of Dr. Avorn) (noting that, for “the important new drugs, you don’t really need to have this big marketing push if it’s a really meaningful clinical advance”).

⁶⁵ Randolph Frankel, a drug marketing specialist and IMS vice president, acknowledged that “provider-level data is [not] the only way to find things out, but it does add another and a significant level of efficiency or effectiveness in terms of how you do it. . . . [I]f these data disappeared, pharmaceutical companies would find some other way to approve how they allocate, how they target, and how they message.”

⁶⁶ Plaintiffs suggest that the Act may result in prescriber-identifiable data becoming completely unavailable, an outcome that all parties would likely consider undesirable. Plaintiffs theorize that the pharmaceutical companies would be unwilling to pay substantial sums for information they cannot use in marketing, eliminating the data miners’ biggest customers – thereby cutting off the commercial funding that subsidizes the research and other non-commercial uses of the data. However, the statute allows many commercial uses of the data and, even where reliance on specific prescriber information is prohibited, the drug companies may rely on permissible forms of aggregated data (by speciality and zip code). Thus, the prospect that prescriber data will no longer be available for any purpose is too speculative to undermine the State’s interest.

be "enough to convince us that the . . . advertising provisions were unconstitutional"); *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 194, 119 S.Ct. 1923, 144 L.Ed.2d 161 (1999) (noting that the statute at issue "sacrifices an intolerable amount of truthful speech about lawful conduct when compared to all of the policies at stake").⁶⁷ Thus, the fact that detailing with prescriber-identifiable data may at times have a positive effect on health care does not negate the Act's role in advancing the State's interest in cost-containment.

C. Narrow Tailoring

In evaluating the narrow tailoring prong of the *Central Hudson* inquiry, the Court typically has asked "whether the extent of the restriction on protected speech is in reasonable proportion to the interest served." *Edenfield*, 507 U.S. at 767, 113 S.Ct. 1792; see also *Greater New Orleans Broad. Ass'n*, 527 U.S. at 188, 119 S.Ct. 1923 ("The Government is not required to employ the least restrictive means conceivable, but it must demonstrate narrow tailoring of the challenged regulation to the asserted interest - 'a fit that is not necessarily perfect, but reasonable'. . .")

⁶⁷ Dr. Avorn offered the following observation: "If they can't make their argument on the basis of the data justifying the use of their drug and it requires knowing the doctor's prescribing habits to make that case, then I would say that's not a case that ought to get made. It ought to be about the data and the merits of the product, not about my professional history."

(quoting *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480, 109 S.Ct. 3028, 106 L.Ed.2d 388 (1989)); *Florida Bar*, 515 U.S. at 632, 115 S.Ct. 2371 (“[T]he ‘least restrictive means’ test has no role in the commercial speech context.”).

This “reasonable fit” standard of intermediate scrutiny has drawn criticism. See *Thompson*, 535 U.S. at 367-68, 122 S.Ct. 1497 (noting that “several Members of the Court have expressed doubts about the *Central Hudson* analysis and whether it should apply in particular cases”); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554-55, 121 S.Ct. 2404, 150 L.Ed.2d 532 (2001) (same); *Greater New Orleans Broad. Ass’n*, 527 U.S. at 184, 119 S.Ct. 1923 (recognizing the advocacy among judges, scholars and others for “a more straightforward and stringent test for assessing the validity of governmental restrictions on commercial speech”).⁶⁸ However, the Court majority has adhered to the *Central Hudson* approach, observing repeatedly that, in the particular case at issue, “there is no need to break new ground” in assessing the validity of the challenged governmental restrictions on commercial speech. See *Thompson*, 535 U.S. at 368, 122 S.Ct. 1497; *Lorillard Tobacco Co.*, 533 U.S. at 554-55, 121

⁶⁸ Justice Thomas has been particularly adamant in contending that no distinction should be drawn between commercial and noncommercial speech: “I do not see a philosophical or historical basis for asserting that ‘commercial’ speech is of ‘lower value’ than ‘noncommercial’ speech. Indeed, some historical materials suggest to the contrary.” 44 *Liquormart*, 517 U.S. at 522, 116 S.Ct. 1495 (Thomas, J., concurring).

S.Ct. 2404; *Greater New Orleans Broad. Ass'n*, 527 U.S. at 184, 119 S.Ct. 1923.

Nonetheless, the debate on *Central Hudson's* continuing viability seems to have influenced the Court's application of its framework. Multiple commentators have observed that intermediate scrutiny under *Central Hudson* has "come to resemble closely the 'narrowly tailored' requirement of strict scrutiny." Troy L. Booher, *Scrutinizing Commercial Speech*, 15 Geo. Mason U. Civ. Rts. L.J. 69, 77 (2004); see also R. Michael Hoefges, *Regulating Professional Services Advertising: Current Constitutional Parameters and Issues Under the First Amendment Commercial Speech Doctrine*, 24 Cardozo Arts & Ent. L.J. 953, 989 (2007) (noting that recent precedent arguably "has pushed the fourth prong of the *Central Hudson* analysis closer than ever before to the least-restrictive-means requirement of strict constitutional scrutiny"); Emily Erickson, *Disfavored Advertising: Telemarketing, Junk Faxes and the Commercial Speech Doctrine*, 11 Comm. L. & Pol'y 589, 602 (2006) ("[T]he broader trend has been one of higher scrutiny for commercial speech cases."); Elizabeth Spring, *Sales Versus Safety: The Loss of Balance in the Commercial Speech Standard in Thompson v. Western States Medical Center*, 37 U.C. Davis L.Rev. 1389, 1404 (2004) ("[T]he Court is now applying the *Central Hudson* test in a manner approaching strict scrutiny review.").

Indeed, in *Thompson*, a 5 to 4 decision, Justice Breyer in dissent chastises the majority for applying

the commercial speech doctrine "too strictly" in striking down a statute prohibiting the advertising of compounded drugs. 535 U.S. at 388, 122 S.Ct. 1497. In finding that the regulation was not narrowly tailored, the majority proposed a variety of non-speech alternatives that the Government could have adopted to meet its objectives. The justices observed that "[i]f the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Id.* at 371, 122 S.Ct. 1497. From Justice Breyer's perspective, however, the majority "too readily assume[d] the existence of practical alternatives." *Id.* at 388, 122 S.Ct. 1497.

This case does not require us to decide if *Thompson* represents a departure in the Court's application of the narrow tailoring prong of *Central Hudson*. As I shall explain, even as applied by the majority in *Thompson*, *Central Hudson*'s narrow tailoring requirement is satisfied here. As an initial matter, the restriction on speech imposed by the Prescription Act is significantly more limited than similar restrictions on commercial speech that have been considered by the Supreme Court. It is neither a complete ban on the marketing or advertising of a product or its price, *see, e.g., Thompson*, 535 U.S. at 360, 122 S.Ct. 1497 (compounded drugs); 44 *Liquormart*, 517 U.S. at 489, 116 S.Ct. 1495 (retail price of alcoholic beverages), nor a blanket prohibition on in-person solicitation, *see, e.g., Edenfield*, 507 U.S. at 763, 113 S.Ct. 1792 (accountants); *Ohralik*, 436 U.S. at 448-49, 98 S.Ct.

1912 (attorneys). Pharmaceutical sales representatives may continue to pitch their drugs directly to doctors and other health care providers, and the only message proscribed is one that incorporates an awareness of the doctor's prescribing practices. The detailers also may continue to use prescriber data provided by the plaintiffs for marketing, so long as the data aggregates prescribing patterns by speciality and zip code and not by individual provider. Thus, this case does not trigger the "special concerns [that] arise from 'regulations that entirely suppress commercial speech in order to pursue a nonspeech-related policy,'" 44 *Liquormart*, 517 U.S. at 500, 116 S.Ct. 1495 (quoting *Central Hudson*, 447 U.S. at 566 n. 9, 100 S.Ct. 2343).

Despite the Act's limited scope, the plaintiffs maintain that it is broader than necessary to serve the State's objective and that it thus fails the narrow tailoring test. For multiple reasons, I reject the plaintiffs' contention and conclude that the State has met its burden of justifying the Prescription Act. The inadequacy of alternatives to satisfy the State's interests, the context of private communications, and the limited impact on the message sought to be disseminated lead me to conclude that New Hampshire has established "a 'reasonable fit' between its abridgment of speech and its . . . goal," 44 *Liquormart*, 517 U.S. at 507, 116 S.Ct. 1495.

1. Inadequacy of Alternative Measures

The plaintiffs argue that the State's cost-containment objective could have been achieved through measures that did not impact protected speech at all. The district court agreed and noted that, for example, the Legislature could have addressed the issue by "properly implementing" a Medicaid Pharmacy Program that takes into account the cost-effectiveness of brand-name drugs. 490 F.Supp.2d at 182. The court pointed out that New Hampshire's current program requires authorization for Medicaid patients to obtain certain drugs and that state regulations allow cost considerations to be taken into account when deciding which drugs should be subject to the authorization. 490 F.Supp.2d at 182. As a result, the court concluded that the State could prevent unnecessary expenditures on brand-name drugs by denying authorization requests for more expensive drugs that are no more effective than cheaper alternatives. *Id.*

This proposal and the other non-speech alternatives proposed by the parties and the district court lack equivalency with the Prescription Act in accomplishing the State's cost-containment goal. In response to the district court's suggestion that legislative changes be made in the Medicaid program, the Attorney General argues that such measures would not respond to the State's broader concern that physicians' drug choices for all patients are distorted

by the detailers' access to prescriber-identifiable data.⁶⁹ In addition, the Attorney General maintains that formularies also are affected by pharmaceutical detailing, citing evidence that physicians request additions to such lists even when the added drugs have "little or no therapeutic advantage over existing formulary drugs." Wazana, *supra*, at 375.

The court's other suggestions – requiring the State "to enter the intellectual marketplace" with its own information about proper drug choices; mandating participation in continuing medical education programs; or limiting the samples, meals and other ingratiating gifts provided by detailers to prescribers – are similarly imperfect. The Attorney General argues that the State lacks comparable resources to directly counter commercial detailing – for which the pharmaceutical companies spend billions of dollars⁷⁰ – and the district court at trial noted Avorn's testimony that relying on medical education programs would be difficult because "it would be hard to find the right

⁶⁹ The plaintiffs elicited testimony that placing drugs on a Medicaid formulary list has a spillover effect on "the cash market" as well, Day 1, PM Session, at 29 (testimony of Hossam Sadek, IMS senior vice president), but the State reasonably could conclude that it could not rely on that secondary impact to achieve its objective.

⁷⁰ She further argues that "such a solution would simply treat the symptom," while the statute "is an effort to treat the disease itself." Brief at 43.

people and . . . [t]here would be disputes over what the content is."⁷¹

I acknowledge that the suggestion that the State prohibit courtesy samples and other gifts to prescribers is not as easily dismissed. That prohibition could be implemented unilaterally and without expense to the State. Like the Prescription Act, such a ban would be directly aimed at diminishing the persuasive force of the detailers' message. As described above, the record contains evidence that the perks have a subtle influence on physicians' decision-making, increasing their affinity for particular sales representatives – and, presumably, for those representatives' drugs. In fact, a number of states have passed laws requiring that gifts to prescribers be publicly disclosed, and, as with the use of prescriber-identifiable data, professional guidelines have been adopted to reduce or eliminate such benefits.

While similar in intent, however, a ban on gifts and the ban on the use of prescriber-identifiable data are not interchangeable means of achieving the State's goal of cost-containment. The samples and gifts are merely a preparatory step in the marketing process; while they may increase the prescribers' susceptibility to the sales pitch, the State reasonably

⁷¹ Avorn testified that the pharmaceutical industry funds about 65 percent of continuing medical education and that one challenge of such an approach would be to decide "[w]ho gets to decide what the right message is."

concluded that it is the sales pitch itself that has the most troubling effect on the prescribers' drug choice – and is most urgently in need of regulation. *See* Appellant's Brief at 42 (asserting that pharmaceutical companies use prescriber-identifiable data "to subtly manipulate physicians, in ways physicians are often unaware, to change their prescriptions for reasons other than the clinical needs of patients") (citing Avorn Declaration, at 9-11).⁷²

Moreover, Avorn testified that the remedies proposed by the district court "have been tried, not necessarily in New Hampshire, in particular, but nationally in terms of trying to restrict the freebies, trying to provide doctors with other means of learning, requiring that doctors take continuing ed courses." Avorn opined that the Prescription Act

was not just a flippant, oh, let's see what happens with this. It was more of a sense of people have tried everything they can try and we still have this massive distortion of what doctors are prescribing and what the State, and its citizens, are paying for drugs because of the very heavily and very effective promotional strategies that are going on out

⁷² I note, in addition, that the State reasonably could reject a ban on samples because free medication allows many individuals to receive more effective treatments than they otherwise could afford. Although the evidence showed that not all doctors favor the distribution of free samples, the benefits of sampling would allow the State to conclude, on balance, that other cost-cutting measures would be preferable.

there; and this seemed like – given that those other avenues are probably not going to be viable, that this seemed to be a way of preserving the company's ability to give me their best shot in their sales argument, but not to do so with a kind of knowledge that really shouldn't have anything to do with teaching me something. . . .

I am thus satisfied that the State has eliminated the possibility that "alternative forms of regulation that would not involve any restriction on speech would be *more likely* to achieve the State's goal," 44 *Liquor-mart*, 517 U.S. at 507, 116 S.Ct. 1495 (emphasis added). To the contrary, Avorn's summary of other initiatives indicates that the State reasonably concluded that its legislation provided the only effective approach for achieving its objective.

In responding to the proposed alternatives through argument and evidence, the Attorney General in this case took steps that the majority in *Thompson* found lacking in the government's presentation there. The Court observed that "[n]owhere in the legislative history of the [Act] or petitioners' briefs is there any explanation of why the Government believed forbidding advertising was a necessary as opposed to merely convenient means of achieving its interests." 535 U.S. at 373, 122 S.Ct. 1497. The Court commented that "there is no hint" that the government had considered the alternatives proposed by the Court, or any other strategies. *Id.* In this case, the State offered expert evidence at trial and argued in

its briefs on appeal in defense of its view that alternative strategies would not suffice. Thus, unlike in *Thompson*, the State has amply rebutted any impression that regulating speech was the first, or only, strategy it thought to try. *Cf. id.*

2. Focus on Private Communications

It is also significant that the Prescription Act restricts only private communications between the pharmaceutical detailer and prescribers, rather than a message disseminated to the public at large. In evaluating whether the Prescription Act advanced the State's cost-containment interest, the district court noted the Supreme Court's rejection in *Thompson* of a government interest "in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." 490 F.Supp.2d at 181 (quoting *Thompson*, 535 U.S. at 374, 122 S.Ct. 1497); see also 44 *Liquormart*, 517 U.S. at 503, 116 S.Ct. 1495 ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.").

This case differs from those in which the Court has rejected advertising bans that restrict the exchange of ideas in the "commercial marketplace." The Prescription Act neither "protects" the public from information about drugs nor prevents truthful advocacy by pharmaceutical representatives. Instead, it

prevents sales representatives from crafting personal marketing messages on the basis of data that credible evidence indicates has been used to unduly influence prescribing choices. The Supreme Court on multiple occasions has reviewed regulation of such direct solicitations, upholding restrictions where the context raised concerns about the impact of the marketing on the recipient. See *Edenfield*, 507 U.S. at 765, 113 S.Ct. 1792 ("There are, no doubt, detrimental aspects to personal commercial solicitation in certain circumstances. . . .").

Two such cases provide a helpful contrast and offer guidance in this case. In *Ohralik*, the Court upheld a bar against in-person solicitation of prospective clients by lawyers in "'situation[s] that breed[] undue influence,'" 436 U.S. at 449, 98 S.Ct. 1912 (quoting *Bates v. State Bar of Ariz.*, 433 U.S. 350, 366, 97 S.Ct. 2691, 53 L.Ed.2d 810 (1977)). *Ohralik* involved two young victims of an automobile accident, one who was approached while she was still hospitalized and the other on the day she was released from the hospital. *Id.* at 450-51, 98 S.Ct. 1912. The Court found that the State's compelling interest in "preventing those aspects of solicitation that involve fraud, undue influence, intimidation, overreaching, and other forms of 'vexatious conduct'" justified the limited restriction on speech. *Id.* at 462, 98 S.Ct. 1912. The Court further observed that "it hardly need be said that the potential for overreaching is significantly greater [than in the sale of ordinary consumer products] when a lawyer, a professional trained in the

art of persuasion, personally solicits an unsophisticated, injured, or distressed lay person." *Id.* at 464-65, 98 S.Ct. 1912.

By contrast, the Court concluded in *Edenfield* that a ban on face-to-face solicitation by certified public accountants ("CPAs") did not survive First Amendment scrutiny. 507 U.S. at 765, 113 S.Ct. 1792. Although noting that face-to-face commercial solicitation may have "detrimental aspects," *id.*, the Court also recognized that, "[i]n the commercial context, solicitation may have considerable value," *id.* at 766, 113 S.Ct. 1792. Among the advantages listed by the Court were "direct and spontaneous communication between buyer and seller," "enabl[ing] the seller to direct his proposals toward those consumers who he has reason to believe would be most interested in what he has to sell," and providing buyers "an opportunity to explore in detail the way in which a particular product or service compares to its alternatives in the market." *Id.* The Court ultimately found that the risks inherent in the *Ohralik* context did not exist in the accountant setting:

Unlike a lawyer, a CPA is not "a professional trained in the art of persuasion." A CPA's training emphasizes independence and objectivity, not advocacy. The typical client of a CPA is far less susceptible to manipulation than the young victim in *Ohralik*. Fane's prospective clients are sophisticated and experienced business executives who understand well the services that a CPA offers. In general, the prospective client has an

existing professional relation with an accountant and so has an independent basis for evaluating the claims of a new CPA seeking professional work.

Id. at 775, 113 S.Ct. 1792 (citations omitted). The Court thus concluded that "the ends sought by the State are not advanced by the speech restriction," and that the rule against in-person solicitation "infringe[d] upon Fane's right to speak, as guaranteed by the Constitution." *Id.* at 777, 113 S.Ct. 1792.

In relevant respects, this case falls between *Ohralik* and *Edenfield*. Although the recipients of the marketing messages at issue here are, unlike in *Ohralik*, highly trained professionals, the solicitor in question – the pharmaceutical detailer – is schooled in the art of persuasion, like the lawyers in *Ohralik*. Unlike in *Edenfield*, there is substantial evidence that the detailer's persuasion has an impact and that confining the marketing interaction in the manner required by the Prescription Act would advance the State's interest. The detailer often has knowledge of drug details that are not readily available to the physician, and the evidence supports the State's view that adding prescriber-identifiable data into the mix lends weight to the detailer's message – and increases the likelihood that the targeted prescriber will choose the brand-name drug being promoted by the detailer.

This is not to suggest that the detailer's message is generally inaccurate or misleading. The advantage provided by prescriber-identifiable data may only be

to refocus the emphasis of the presentation. But where the record shows a real risk that "one-sided" presentations may give marketers "undue influence," the appropriateness of limiting speech veers much closer to *Ohralik* than *Edenfield*. See *44 Liquormart*, 517 U.S. at 498, 116 S.Ct. 1495 (commenting that the State "may restrict some forms of aggressive sales practices that have the potential to exert 'undue influence' over consumers"); *Ohralik*, 436 U.S. at 462, 98 S.Ct. 1912 (noting state's legitimate interest in "preventing those aspects of solicitation that involve fraud, *undue influence*, intimidation, overreaching, and other forms of 'vexatious conduct'") (emphasis added).

3. Calculation of Costs and Benefits

I already have described the alternative ways in which prescribers will have access to the helpful information that may no longer be available to them from pharmaceutical detailers as a result of the Prescription Act. See *supra* Section IV.B.2.b. The statute therefore suppresses only a small amount of beneficial speech. "On the whole, then, the challenged regulation . . . indicate[s] that [the State] "carefully calculated" the costs and benefits associated with the burden on speech imposed by its prohibition.'" *Greater New Orleans Broad. Ass'n*, 527 U.S. at 188, 119 S.Ct. 1923 (quoting *Discovery Network*, 507 U.S. at 417, 113 S.Ct. 1505 (quoting *Fox*, 492 U.S. at 480, 109 S.Ct. 3028)); see also *U.S. West, Inc.*, 182 F.3d at 1238.

In this context, I conclude that the State has met its burden to justify the limited restraint on commercial speech imposed by the Prescription Act.⁷³

V.

There remains the plaintiffs' Commerce Clause challenge to the Act. I part company with my colleagues on that challenge because the majority's discussion of the issue, and its ready acceptance of the Attorney General's statement about the scope of the Act, further undermine the value of the majority's decision. There is a puzzling disconnect between the Attorney General's contention that the Act governs only transactions that take place within New Hampshire and the plaintiffs' contention that all of the conduct that the Act purports to regulate occurs outside the State. On the record before us, we do not have an adequate foundation for evaluating that disconnect and its implications for the Commerce Clause analysis. I therefore would remand this case to the district court with instructions to address the Commerce Clause issue in the first instance.⁷⁴

⁷³ I join the majority's discussion of the plaintiffs' contention that the statute is unconstitutionally vague, other than its statement in footnote 9 invoking standing doctrine.

⁷⁴ The district court's First Amendment ruling made it unnecessary for it to evaluate the parties' legal arguments concerning the vagueness and Commerce Clause challenges.

Under the Attorney General's interpretation of the statute – that the Act reaches only transactions that occur within New Hampshire – no Commerce Clause problem would exist. See *Alliance of Auto. Mfrs. v. Gwadowsky*, 430 F.3d 30, 35 (1st Cir.2005) (explaining that, in evaluating whether a statute has impermissible extraterritorial reach, courts are obliged to adopt any reasonable construction consistent with the Constitution). The majority summarily deems that narrowing construction “reasonable,” commenting that “it would make no sense to read the statute to regulate out-of-state transactions when the upshot of doing so would be to annul the statute.” Yet a literal application of that narrowing construction would appear to leave the Act with negligible impact – hardly a reasonable outcome.

It is undisputed that none of the *plaintiffs'* transactions take place within New Hampshire. The district court found that “IMS and Verispan obtain all of their prescription information, including information on prescriptions filled in New Hampshire, from computers that are located outside of New Hampshire.” 490 F.Supp.2d at 166. At trial, the court described the factual record on the Commerce Clause question as follows:

It's undisputed that prescriptions are generated in the state. It's undisputed that the prescriptions are filled within the state. It's undisputed that the pharmacies where they're filled [are] based in the state. It's undisputed that the pharmacy, as a part of its

routine practices, unassociated with the sale of this information to pharmaceutical companies or IMS, transfers the information in the ordinary course of its business from a data center in the state to data centers outside the state. That the IMS software and Verispan software is applied to it outside the state. That it is then transferred from the [pharmacy] to IMS or Verispan outside the state, and it is thereafter sold to pharmaceutical companies and other clients outside the state.

The parties agreed that this summary, with some variations, was accurate and also agreed with the court's understanding that "the factual record that bears on the Commerce Clause question is undisputed."

Given these undisputed facts, however, it is unclear how much, if any, of the activity that the statute explicitly proscribes occurs within New Hampshire. For example, the "routine" transfer of prescriber-identifiable information from a local New Hampshire pharmacy to the pharmacy's out-of-state headquarters does not appear to be prohibited by the Act. Arguably, that electronic transfer would not be for an impermissible "commercial purpose" – involving, *inter alia*, "advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales

force." Consequently, the data would be outside New Hampshire before any transaction described by the Act occurs. The district court's factual summary suggests that most prescriber-identifiable data leaves New Hampshire in this permissible manner.

That understanding of the facts underlies the plaintiffs' argument that the Act seeks to prohibit the licensing, transfer, use, or sale of data identifying New Hampshire prescribers *wherever such activity occurs*. Plaintiffs' counsel explained their position during a colloquy with the court at trial:

The State has said, this doesn't apply outside of the state. . . . [O]ur reply to that has been . . . if it doesn't prohibit these transactions outside of the state, then the statute really loses all of its force and effectiveness. Because if Rite Aid's pharmacy in New Hampshire can transfer to its parent in Pennsylvania and its parent can transfer to IMS or Verispan in Pennsylvania, that's not prohibited. And then they can transfer it to Pfizer, wherever Pfizer's headquarters are outside of New Hampshire; and if Pfizer can then use it outside of New Hampshire for all of these various purposes that are prohibited, then there's absolutely no force or effect to this statute. And I think what the State is really arguing is that . . . all these transfers outside of the state, they are prohibited.

This statement stops one step short of demonstrating the most critical flaw in the Attorney General's narrowing construction of the Act. If her view of the Act

were correct, not only could Pfizer buy and use New Hampshire data *outside* of New Hampshire "for all these various purposes that are prohibited," but the Act also would pose no barrier to the use of such data by detailers *inside* New Hampshire. This would be so because the Act does not apply to detailers and, as noted above, the undisputed facts suggest that the detailers routinely obtain the data from entities whose acquisition of the information, according to the Attorney General, was not restricted by the Act. Hence, the detailers' use of prescriber-identifiable data in New Hampshire doctors' offices would appear to involve no violation of the Prescription Act. In taking an indirect route toward its goal of regulating detailers' communications, presumably to avoid the First Amendment concerns that would be triggered by a direct restriction on speech, the Legislature may not have accomplished what it intended.

Of course, the Attorney General may believe that her concession that the Act does not apply to out-of-state transactions is not problematic because of her view that the Act bars detailers from using prescriber-identifiable data in their communications with New Hampshire prescribers if that data *originated* in New Hampshire, regardless of whether the pharmaceutical company purchased the information inside or outside of the state. Indeed, that understanding of the Act's scope is suggested by the Attorney General's comments during the parties' colloquy with the district court:

The reality of the situation here is we have . . . national chain pharmacies moving into the State of New Hampshire, setting up their own places of business, hiring pharmacists, hiring managers, establishing a place of business in the State of New Hampshire and then obviously agreeing to abide by the laws of the State of New Hampshire when they establish a place of business in this state; and then in the course of their business, they're collecting . . . these data. They're moving these data out of the state, for whatever purpose, in full knowledge of . . . the laws of the State of New Hampshire. . . .

Under this view of the law, New Hampshire places an embargo on the use of the prescriber-identifiable data before it is first released by the pharmacies. The Attorney General apparently contemplates that New Hampshire pharmacies and similar entities would be permitted to license, transfer, use or sell the information they accumulate only on the condition that the data not be used downstream for the prohibited commercial purposes.

However, the disconnect that I described earlier remains. The explicit language of the Act does not appear to impose such a restriction on the original transfers of data by New Hampshire pharmacies to entities outside the state. The Act proscribes only the transfer of prescriber-identifiable data for the specified commercial purposes. The transfer of data by New Hampshire pharmacies beyond New Hampshire's borders typically may not implicate those

prohibitions. Transactions involving those commercial purposes occur farther downstream, and, so far as the record shows, primarily outside the state. Frankly, I am not sure that the Attorney General understood the import of her statement that the Act regulates only in-state transactions. Nor, given the state of the record, do I understand the majority's statement that, when the Act is interpreted as the Attorney General proposes, it "may result in a loss of profit to out-of-state data miners due to the closing of one aspect of the New Hampshire market for their wares." To the contrary, the statute's impact in New Hampshire appears negligible if it truly governs only transactions that occur within the state.

Although the Attorney General's concession was an attempt to sidestep the plaintiffs' Commerce Clause challenge, there may be an argument that such a step was unnecessary. When a state statute regulates commerce "wholly beyond the boundaries of the enacting state," it usually is invalid per se. *Alliance of Auto. Mfrs.*, 430 F.3d at 35. Yet not every impact on interstate commerce is prohibited. "[T]he dormant Commerce Clause[] is not absolute and in the absence of conflicting legislation by Congress, 'the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected.'" *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 311 (1st Cir.2005) (quoting *Maine v. Taylor*, 477 U.S. 131, 138, 106 S.Ct. 2440, 91 L.Ed.2d 110 (1986)). Moreover, whether extraterritoriality is

impermissible in every instance, or whether it transgresses the dormant Commerce Clause only when the challenged statute is discriminatory or protectionist in nature, appears to be another relevant consideration. See Peter C. Felmly, Comment, *Beyond the Reach of States: The Dormant Commerce Clause, Extraterritorial State Regulation, and the Concerns of Federalism*, 55 Me. L.Rev. 467, 491 (2003) (noting that recent Supreme Court cases considering the dormant Commerce Clause suggest an increased "focus on the territorial reach of state legislation . . . in stark contrast to the long-established concentration on state regulations that are discriminatory or protectionist in nature").

I have said enough to demonstrate the complexity of the Commerce Clause issue and the inadequacy of the record. There are missing details about how the prescriber-identifiable data generated by New Hampshire pharmacies flows to corporate offices out of state and the purpose of that information flow. The parties appear to have different assumptions about those details and their legal significance. Moreover, the plaintiffs' argument on the Commerce Clause spans only two and one-half pages in their sixty-page brief. The Attorney General's response is equally terse. I think it unwise to address the Commerce Clause issue based on a cursory briefing that provides neither legal analysis nor developed application of the law to the limited facts of record. Although the parties agreed at trial that the facts on the Commerce Clause claim were undisputed and that no further

evidence was needed to resolve it, the plaintiffs do not address that evidence in any meaningful way in their briefs and the Attorney General does not address the evidence at all. The district court did not reach the claim.

Our comment about a similarly bare Commerce Clause claim in *Wine & Spirits II* also should guide us here: "This sophisticated area of law requires developed argumentation, with evidentiary support." 481 F.3d at 15 (noting that the Supreme Court had "label[ed] as a 'critical consideration' regarding extraterritorial reach claims the 'overall effect of the statute on both local and interstate commerce'" (quoting *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 337 n. 14, 109 S.Ct. 2491, 105 L.Ed.2d 275 (1989))). I therefore would remand this case to the district court on the Commerce Clause issue.

VI.

I summarize my conclusions:

1. The prudential standing doctrine is inapplicable in the circumstances of this case, where the core First Amendment issue was vigorously litigated and comprehensively considered by the district court, and where the Prescription Information Act's constitutionality cannot be assessed without addressing its impact on the communications between detailers and prescribers;

2. The Act restricts commercial speech that is protected by the First Amendment, and the Attorney General therefore bears the burden of demonstrating that the statute satisfies the *Central Hudson* test;

3. Although the State has failed to prove that the Act is justified by substantial interests in privacy and quality health care, it has met its burden to show that the Act directly advances its interest in containing the cost of prescription drugs and is not more extensive than necessary to accomplish that objective.

4. Like the majority, I find the Prescription Act sufficiently clear to withstand plaintiffs' vagueness challenge when construed narrowly, consistent with its legislative history and applicable precedent.

5. The plaintiffs' contention that the Act violates the dormant Commerce Clause should be considered by the district court in the first instance. We should remand the case for that purpose.

490 F.Supp.2d 163

United States District Court,
D. New Hampshire.
IMS HEALTH INCORPORATED, et. al.

v.

Kelly AYOTTE, as Attorney General of the
State of New Hampshire.

No. 06-cv-280-PB.

April 30, 2007.

James P. Bassett, Jeffrey C. Spear, Orr & Reno PA,
Concord, NH, Mark A. Ash, Smith Anderson Blount
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General's Office, Department of Justice, Concord,
NH, for Kelly Ayotte, as Attorney General of the State
of New Hampshire.

MEMORANDUM AND ORDER

BARBADORO, District Judge.

A lucrative market has developed in recent years for data identifying the prescribing practices of individual health care providers ("prescriber-identifiable data"). Pharmacies acquire prescription data in the ordinary course of business. Data mining companies such as the plaintiffs in this case, IMS Health Incorporated and Verispan, LLC, purchase the prescription

data, remove information identifying patients before it leaves the pharmacy, combine what remains with data from other sources, and sell the combined data to interested purchasers. The data miners' biggest clients by far are pharmaceutical companies, which use the data to develop marketing plans targeted to specific prescribers.

The New Hampshire Legislature recently enacted a law that bars pharmacies, insurance companies, and similar entities from transferring or using prescriber-identifiable data for certain commercial purposes. See 2006 N.H. Laws § 328, codified at N.H.Rev.Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006) ("Prescription Information Law"). IMS and Verispan have filed this action contending that the new law impermissibly restricts their First Amendment right to free speech.

In this Memorandum and Order, I explain why the new law violates the First Amendment.

I. *FACTS*¹

A. Prescription Information Collection

Approximately 1.4 million licensed health care providers are authorized to write prescriptions in the United States for approximately 8,000 different

¹ All factual findings in this Memorandum and Order are based on evidence produced at trial. The facts have been established by a preponderance of the evidence.

pharmaceutical products in various forms, strengths, and doses. These prescriptions are filled by approximately 54,000 retail pharmacies and other licensed medical facilities throughout the United States.

Retail pharmacies acquire prescription data during the regular course of business. For each prescription filled, a record is kept that includes the name of the patient, information identifying the prescriber, the name, dosage, and quantity of the prescribed drug, and the date the prescription was filled. If the pharmacy is part of a larger organization with multiple retail outlets, each outlet's prescription data is ultimately aggregated with data from other outlets and stored in a central location.

B. Plaintiffs' Acquisition of Prescription Information

IMS and Verispan are the world's leading providers of information, research, and analysis to the pharmaceutical and health care industries. IMS, the largest business in the field, purchases prescriber information from approximately 100 different suppliers. Verispan, a company roughly one-tenth the size of IMS, obtains its information from approximately thirty to forty suppliers. Plaintiffs collectively acquire and analyze data from billions of prescription transactions per year throughout the United States.

Plaintiffs purchase prescriber-identifiable data from participating pharmacies and other sources. To comply with state and federal laws protecting patient

privacy, participating pharmacies allow plaintiffs to install software on their computers that encrypts any information identifying patients before it is transferred to plaintiffs' computers. After patient information is "de-identified" in this way, a number is assigned to each de-identified patient that permits prescription information to be correlated for each patient but does not allow the patient's identity to be determined. The prescription information is then transferred to the plaintiffs' computers where it is combined with data from other sources and made available to plaintiffs' customers. IMS and Verispan obtain all of their prescription information, including information on prescriptions filled in New Hampshire, from computers that are located outside of New Hampshire.

One way in which plaintiffs add value to prescriber-identifiable data is to combine it with prescriber reference information. This allows plaintiffs to, among other things, match each prescription to the correct prescriber, identify and use the prescriber's correct name, and add address, specialty, and other professional information about the prescriber to the prescription data. Prescriber reference files are created using information obtained from various sources, including the American Medical Association's ("AMA") Physician Masterfile. The AMA's Masterfile contains demographic, educational, certification, licensure, and specialty information for more than 800,000 active U.S. medical doctors and over 90 percent of osteopathic doctors. Plaintiffs use

the patient de-identified prescription data, together with the reference file data, to produce a variety of patient de-identified databases.

The AMA recently adopted a program that gives participating health care providers the power to limit access to their prescribing information ("the Prescribing Data Restriction Program" or "PDRP"). Under the PDRP, pharmaceutical companies are permitted to acquire prescriber-identifiable data for participating providers but they may not share the information with their sales representatives. IMS and Verispan participate in the PDRP and require their customers to abide by its terms.

C. Uses of Prescription Information by Pharmaceutical Companies

Plaintiffs' biggest clients by far are pharmaceutical companies. According to IMS's 2005 Annual Report, "[s]ales to the pharmaceutical industry accounted for substantially all of [IMS's] revenue in 2005, 2004 and 2003." Approximately 95 percent of Verispan's sales of prescriber-identifiable data are to pharmaceutical companies. Plaintiffs also provide prescriber-identifiable information to biotechnology firms, pharmaceutical distributors, government agencies, insurance companies, health care groups, researchers, consulting organizations, the financial community, manufacturers of generic drugs, pharmacy benefit managers, and others. Some of these entities use, license, sell, or transfer the information

for advertising, marketing, and promotional purposes, while others use the information for non-commercial purposes.²

Pharmaceutical companies commit vast resources to the marketing of prescription drugs. In 2000, the pharmaceutical industry spent approximately \$15.7 billion on marketing, \$4 billion of which was dedicated to direct-to-physician strategies. More recent estimates suggest the industry currently spends between \$25 billion and \$30 billion per year on marketing. The large pharmaceutical companies spend roughly 30 percent of their revenues on promotion, marketing, and administration, while spending only approximately 13 percent on research and development.

Pharmaceutical companies market to both consumers and prescribers. Companies rely primarily on print and television advertising to reach consumers and depend more heavily on a variety of direct marketing techniques to reach health care providers. Among the companies' direct marketing practices that are most relevant to this case are their efforts to enlist the support of "thought leaders" in the medical

² Plaintiffs also make prescriber-identifiable data available at little or no cost for non-marketing purposes to academic researchers, medical researchers, humanitarian organizations, and law enforcement authorities. These entities use the information to track patterns of disease and treatment, conduct research and clinical trials, implement best practices, and engage in economic analyses.

community and their use of "detailing" to persuade individual health care providers to prescribe specific brand-name drugs.

1. *Thought Leaders*

Thought leaders are physicians and researchers whose views are accorded special weight in the medical community. Pharmaceutical companies enlist the support of thought leaders by sponsoring their research, retaining them to serve as consultants and speakers, and entertaining them at dinners and other events. Although thought leaders rarely, if ever, are paid to endorse particular drugs, their tacit support is deemed by pharmaceutical companies to be highly valuable in persuading others to prescribe their products.

2. *Detailing*

Pharmaceutical detailing generally involves the provision of promotional and educational information during face-to-face contact between sales representatives and health care providers. Sales representatives provide prescribers with both written and oral information about particular drugs in an effort to persuade them to prescribe the drugs being detailed. They also offer prescribers free samples that can then be distributed to patients at no charge. Because many prescribers are reluctant to meet with sales representatives, small gifts, free meals, and other inducements are also frequently offered to health care

providers and their staffs in an effort to facilitate access and encourage receptivity to the representative's sales pitch.

a. Promotional Information

Pharmaceutical companies strictly control the information that detailers are authorized to present on their behalf. Although sales representatives generally provide prescribers with accurate information, misstatements and omissions do occur. A 1995 study published in the *Journal of the American Medical Association* concluded that 11 percent of the in-person statements made to physicians by pharmaceutical sales representatives contradicted information that was readily available to them.³ Michael G. Ziegler, Pauline Lew, and Brian C. Singer, *The Accuracy of Drug Information From Pharmaceutical Sales Representatives*, 273 JAMA 1296, 1296-98 (1995).

³ For purposes of the study, an inaccurate statement was defined as one that met all three of the following criteria: (i) the statement clearly contradicted prescribing information in the 1993 Physicians' Desk Reference or literature quoted or handed out by the detailer; (ii) a pharmacist and a physician-clinical pharmacologist independently assessed the statement as incorrect; and (iii) a search of reference books, drug company brochures, and MEDLINE files from 1985 through 1993 provided no support for the statement. Seven of twelve pharmaceutical sales representatives in the study made a total of twelve inaccurate statements in their presentations. All twelve inaccurate statements were about the drug being promoted, and all cast that drug in a favorable light. 273 JAMA at 1296-98.

The Federal Food and Drug Administration ("FDA") has broad authority to regulate drug advertisements and promotional labeling. *See, e.g.*, Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a), 352 (2000); FDA Prescription Drug Advertising Rule, 21 C.F.R. § 202.1 (1999). Existing regulations prohibit prescription drug advertising and labeling information that is false, misleading, or that lacks a "fair balance between information relating to side effects and contra-indications and information relating to effectiveness" 21 C.F.R. § 202.1(e)(5)-(6). The agency is authorized to take enforcement action against companies that use false and misleading advertising materials. 21 U.S.C. §§ 332-337. This regulatory authority also extends to oral misrepresentations by sales representatives. *See, e.g.*, FDA Priv. Ltr. Warning, available at <http://www.fda.gov/cder/warn/sep2000/dd9199.pdf> (warning to cease false and misleading oral statements by sales representatives).

b. Sampling

Product sampling is widely used in the marketing of prescription drugs. Published reports estimate that the total annual retail value of sampled drugs exceeds \$11 billion. Product sampling programs permit sales representatives to use sampled drugs as inducements to facilitate access to prescribers. They also promote sales by allowing prescribers to become familiar with the sampled drugs and by increasing the likelihood that patients will continue to request

prescriptions for sampled drugs after their samples have been consumed. Many physicians accept samples because it allows them to provide free medications to patients who might not otherwise be able to afford them.

c. Gifts, Meals and Other Inducements

Prescribers are often reluctant to meet with sales representatives. In an effort to overcome this reluctance, sales representatives provide health care providers and their staffs with small gifts, free meals, and other inducements. In addition to facilitating access, such inducements help sales representatives build relationships with prescribers that can make them more receptive to the product information that sales representatives provide.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") has adopted a voluntary "Code on Interactions with Health care Professionals," available at <http://www.phrma.org/files/PhRMACode.pdf>, in an effort to address public concern with gift-giving by sales representatives. The 56-page Code contains aspirational guidelines that are intended to ensure that "[i]nteractions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education." *Id.* at 5. Although the PhRMA Code permits members to hire health care providers to serve as consultants and

speakers, *id.* at 10-13, it discourages members from otherwise offering inducements directly to health care providers unless either the value of what is provided is insubstantial (less than \$100) and the inducement is primarily for the benefit of patients, or the value of the inducement is minimal and the inducement is directly related to the provider's practice. *Id.* at 17. For example, an occasional gift of a stethoscope is acceptable under the Code because it is not deemed to be of substantial value and the gift benefits patients. *Id.* at 23. In contrast, an unrestricted gift certificate to a local bookstore may not be offered under the Code regardless of its value because it does not benefit patients and is unrelated to the health care professional's practice. *Id.* at 33. The Code draws similar distinctions with respect to meals and entertainment. *Id.* at 28-37.

Pharmaceutical companies are not obligated to follow the PhRMA Code in New Hampshire. Nevertheless, the United States Department of Health and Human Services, Office of Inspector General ("OIG") has endorsed the Code in guidance it has offered to companies concerning the need for internal compliance programs in the health care industry. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed.Reg. 23731-01 (proposed May 5, 2003). As the guidance states, "[a]lthough compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to

comply with the applicable federal health care program requirements." *Id.*⁴

d. Effectiveness of Detailing

Detailing is generally used only to market prescription drugs that are entitled to patent protection. After the patents on a brand-name drug expire, competitors can obtain approval to sell generic bioequivalent versions of the drug. Generic drugs are generally substantially less expensive than their brand-name equivalents, and bioequivalent generic drugs are equally effective for most patients.⁵ New

⁴ The anti-kickback statute, 42 U.S.C. § 1320a-7b(b)(2), makes it a federal crime to pay a health care provider to order something for which payment may be made under a federal health care program.

⁵ In some circumstances, a brand-name drug may be preferable to a bioequivalent generic alternative. This is primarily because generic drugs are not subjected to the same rigorous study and testing as brand-name drugs, may have unknown side effects, and bioequivalent generic alternatives need only demonstrate absorption parameters falling between 80 and 125 percent of those obtained by their branded counterparts. As a result, individual responses to treatment may vary significantly. For example, when patients switch from a brand-name drug to a generic drug, there is a risk that the patient will absorb significantly more or less of the medication than the patient was absorbing from the branded drug. Additionally, because there may be numerous generic producers of a single brand-name drug, with each generic alternative characterized by a different rate of absorption of active ingredients and different side effects, a patient's response to treatment may vary substantially depending on the generic alternative the pharmacist has in stock on a particular day. In treating epilepsy, for example, these

(Continued on following page)

Hampshire law authorizes pharmacies to substitute a bioequivalent generic drug for a branded drug unless the prescriber specifies that the brand-name drug is "medically necessary." N.H.Rev.Stat. Ann. § 318:47-d(2003). Accordingly, sales of brand-name drugs tend to fall substantially after bioequivalent generic drugs become available and detailing is no longer seen as a cost-effective marketing technique.

Pharmaceutical companies continue to heavily market brand-name drugs as treatments for conditions that can also be treated with generic alternatives that are not bioequivalent. For example, although depression can be treated for many patients with a generic form of Prozac, several pharmaceutical companies also market different brand-name medications as a treatment for depression. Because brand-name medications are often substantially more expensive than non-bioequivalent generic alternatives, those patients who achieve the same benefits from a non-bioequivalent generic medication can save money by substituting the non-bioequivalent generic medication for a branded alternative.

Detailing can be an effective marketing technique for brand-name drugs. It works by, among other things: (i) building name recognition among prescribers for the drug being detailed; (ii) providing

variations may result in the patient experiencing seizures that might have been avoided if the absorption rate had remained steady.

information about the drug to prescribers in a form that is designed to be persuasive; and (iii) providing inducements to providers consisting of free samples, small gifts, and meals that facilitate access and foster relationships between the sales representatives and health care providers.

D. Uses of Prescriber-Identifiable Information in Detailing

Pharmaceutical companies use prescriber-identifiable data for a variety of purposes. I focus here on the ways in which it is used to target prescribers for detailing, to tailor detailing messages, and to evaluate the effectiveness of detailing practices.

1. Targeting

Pharmaceutical companies use prescriber-identifiable data to analyze the prescribing practices of specific health care providers. For example, companies use prescriber-identifiable information when introducing new drugs to identify "early adopters" who have demonstrated by their past prescribing practices that they are disposed to prescribe new medications. They also use prescriber-identifiable data to identify health care providers who have recently changed their prescribing practices with respect to specific drugs, those who are prescribing large quantities of the drugs that the detailer is selling, and those who are prescribing competing

drugs. Targeting health care providers in this manner enables pharmaceutical companies to efficiently allocate resources by providing samples to and detailing for those providers who are most likely to be responsive to detailing for specific products.

2. Tailoring

Pharmaceutical companies use prescriber-identifiable data to tailor their marketing messages to specific health care providers. For example, a sales representative might mention during a detailing session that the drug she is detailing does not have a specific side effect that is associated with a competing drug that the health care provider is currently prescribing. There is no evidence in the record, however, to suggest that pharmaceutical companies use prescriber-identifiable data to facilitate the distribution of false or misleading information.

3. Measuring the Effectiveness of Detailing

Yet another use of prescriber-identifiable data is to measure the effectiveness of detailing. Companies use the data to identify the ratio of brand-name to generic drugs prescribed, assess the success of or resistance to detailer visits, and measure the effectiveness of larger marketing campaigns. In this way, manufacturers can adjust the marketing message that detailers bring to individual health care providers.

E. *The Statute*

The Prescription Information Law became effective on June 30, 2006 and is codified at N.H.Rev.Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006). It expressly prohibits the transmission or use of both patient-identifiable data and prescriber-identifiable data for certain commercial purposes.⁶ The pertinent language of the statute reads:

Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness

⁶ Plaintiffs do not challenge the law's restriction on the transmission and use of patient-identifiable data.

of a professional pharmaceutical detailing sales force. . . .

The statute does not regulate the transmission or use of data for non-commercial purposes. Further, although it defines "commercial purpose" broadly, it expressly excludes from the statute's scope all conceivable commercial uses of the data except those that are directly associated with advertising and marketing. Nor does it prohibit pharmaceutical companies from using prescriber-identifiable data in clinical trials. Violations of the statute are punishable as a misdemeanor if the offender is a natural person and are treated as a felony if the offender is any other person. Violators of the statute are also subject to civil penalties. N.H.Rev.Stat. Ann. § 318:55.

F. Legislative History

The Prescription Information Law was introduced on January 4, 2006, as House Bill 1346 by New Hampshire Representative Cindy Rosenwald. On May 11, 2006, following House and Senate hearings, the New Hampshire Legislature passed the amended bill, which the Governor signed into law on June 30, 2006. The law is the first of its kind in the United States.

According to the law's legislative history, the legislature passed the law to protect patient and physician privacy and to save the State, consumers, and businesses money by reducing health care costs.

An Act Requiring Certain Persons To Keep the Contents of Prescriptions Confidential: Hearing on H.B. 1346 Before the S. Comm. on Exec. Departments & Administration, 159th Sess. Gen. Ct. 1 (N.H.2006) (statement of Rep. Cindy Rosenwald, Member, House of Representatives).

Following passage in the House by a unanimous vote, various representatives spoke in support of the bill at a Senate Committee hearing. According to Representative Rosenwald, the law would accomplish its goals by prohibiting the sale or use of individual patient or prescriber-identifiable information for marketing brand-name prescription drugs. *Id.* A section of a written attachment to Representative Rosenwald's testimony entitled "What H.B. 1346 will do," states that the law will "hopefully reduce the prescription drug costs for patients, employers & the State Medicaid program." *Id.* at Attachment 1.

Representative Pamela Price also testified at the hearing and compared the annual costs to Medicaid of a branded calcium channel blocker and a generic calcium channel blocker to purportedly demonstrate state savings that would occur under the law. *Id.* at 6, Attachment 4 (chart and statement of Rep. Pamela Price, Member, House of Representatives). She claimed that a one-year supply of the branded drug Dynacirc would cost Medicaid \$1,047, while a one-year supply of the generic drug Verapamil would cost Medicaid only \$162. *Id.* Because Medicaid insures a hundred thousand patients, she said, the potential cost savings could be substantial. *Id.*

Representative Price also submitted a short research paper written by Emily Clayton, a health care advocate for the California Public Interest Research Group (CALPIRG). *Id.* at Attachment 13; Emily Clayton, *Tis Always The Season For Giving: A White Paper on the Practice and Problems of Pharmaceutical Detailing*, CALPIRG, Sept. 2004, available at <http://calpirg.org/reports/TistheSeasonForGiving04.pdf>. In the report, Clayton briefly explained that pharmaceutical companies purchase aggregated prescriber information from data mining companies and then use it “to specifically target their sales pitches when they meet with doctors.” *Id.* at 3.

She described the size and growth of the pharmaceutical marketing industry, the competitiveness of detailing, and the effective use of gifts as inducements. Based on Clayton’s review of several other studies that were not a part of the legislative record, she concluded that detailing causes public mistrust of prescriber decisions, increased drug costs, and the provision of incomplete and/or misleading information to prescribers. *Id.* at 4-5. Next, she outlined the AMA and PhRMA guidelines and the OIG’s related guidance, and criticized them as overly narrow, vague, discretionary, and lacking in enforcement mechanisms. To address these problems, she advocated three potential solutions: (i) caps and bans on gifts from pharmaceutical manufacturers to doctors, (ii) disclosure requirements with respect to all gifts from pharmaceutical manufacturers to doctors, and

(iii) codification and enforcement of existing guidelines.

A representative of the Department of Health and Human Services ("DHHS") briefly discussed the large commercial market for prescriber-identifiable data, and said that commercial use of this information violates prescribers' "trade secrets." *Id.* at 9 (statement of Gregory Moore, representative of the DHHS, speaking on behalf of Commissioner John Stephen). According to Moore, the DHHS

believes that these activities ultimately drive up the cost of prescription drugs and the cost of health care in the aggregate. Since no other state has passed legislation like this, it would be hard for us to quantify what that impact might be, but I find it unlikely the drug companies are sending detail[ers] into doctors' offices for the purpose of selling doctors cheaper medication. In fact, I'm confident that, if you're a doctor, that one of the best ways to get a detailer into your office would be if you switched to prescribing a generic drug over a branded drug.

Id. at 8.

In addition, President-elect of the New Hampshire Medical Society, Dr. Seddon Savage, said the law "will deter marketing intended to manipulate the practice of individual physicians that is intended to increase market share for the individual companies, possibly at the expense of appropriate decision-making for the patients." *Id.* at 16-17. Janet Monahan, also

representing the New Hampshire Medical Society, said that because pharmaceutical companies focus their marketing efforts on their newest, most expensive medicines, successful promotions lead to higher health care costs. *Id.* at 27, Attachment 13 (discussing *Clayton, supra*). Bill Hamilton, an advocacy director for AARP said "we did an analysis and we don't feel [the law] necessarily will increase the cost of drugs." *Id.* at 21.

According to testimony offered at this hearing, some detailers use prescriber-identifiable information to put improper pressure on prescribers. One anecdote shared by a nurse practitioner speaking in favor of the Prescription Information Law highlights this alleged problem.

For the past several months, a drug rep has been bringing coffee to our office on Tuesday mornings. We have never asked her to continue doing this since we have a coffee pot, and we routinely make coffee for our staff and our patients. But she does it anyway, which is very nice of her. She calls this "Two for Tuesday." The problem is that every week she also says to me, "If you don't write 2 more prescriptions for my brand today, I'm not going to be able to continue bringing coffee." I prescribe her drug when it is right for my patients. There are many times when it is not right.

We feel pressure from her to prescribe her product even though we have never asked her to bring coffee. This may sound like a

small thing, but I feel that since she knows exactly how many prescriptions I write each week for her drug versus the competition, she is expecting a quid pro quo.

Id. at 33, Attachment 15. A similar anecdote, as described in a January 2006 article in The New York Times, was also included in the legislative record. According to the article, a district manager for a pharmaceutical company sent an e-mail to detailers in which she stated that

[o]ur goal is 50 or more scripts per week for each territory. If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs, and past preceptorships⁷ that you have provided or paid for and get the business!! You can do it!!

Id. at 27, Attachment 13 (quoting Gardiner Harris & Robert Pear, *Drug Maker's Efforts to Compete in Lucrative Insulin Market Are Under Scrutiny*, N.Y. TIMES, Jan. 28, 2006).

Others spoke in opposition to the bill. A representative of the New Hampshire Association of Chain Drug Stores expressed concern that the bill struck too broadly and, among other problems, would prevent prescriptions from being transferred from one

⁷ Preceptorships are consulting arrangements with doctors.

pharmacy to another. *Id.* at 11. Representatives of IMS Health and Verispan also spoke in opposition, arguing that the law would do nothing to advance patient privacy, that prescriber privacy could be adequately addressed by the PDRP,⁸ and that the legislature should consider other ways to address privacy concerns to avoid losing out on the value of prescriber-identifiable information. *Id.* at Attachment 10. They suggested that the law would cause unintended harms, including increased health care costs caused by the need for higher drug prices to make up for inefficient marketing, inefficient sampling, and increased compliance and enforcement costs. *Id.* at 22, Attachment 12.

G. The Statute's Impact

IMS and Verispan have substantially altered their business practices to comply with the Prescription Information Law. IMS has entered into agreements with its sources of prescription information to ensure that it will not use the information in ways that violate the law. It removes prescriber-identifiable information from New Hampshire prescriptions and no longer sells prescriber-identifiable data from New Hampshire to third parties. To avoid inadvertent violations, it examines every prescription record it receives and removes all identifying data

⁸ As of the time of the hearing, the PDRP was not yet in place.

for prescriptions that originate from a pharmacy or a health care provider with a New Hampshire zip code. Verispan has modified its databases so that it can identify and suppress all prescriber-identifiable data from New Hampshire prescriptions before the information is released to third parties.

II. ANALYSIS

Plaintiffs argue that the Prescription Information Law is a content-based restriction on non-commercial speech that is subject to strict scrutiny. They then assert that the law violates the First Amendment because it is not narrowly tailored to serve compelling state interests. Their fall-back position is that the law is unconstitutional even if it is a commercial speech restriction subject only to intermediate scrutiny because it does not directly advance a substantial governmental interest in a manner that is narrowly tailored to serve that interest.

The Attorney General attacks the plaintiffs' claim at every turn. She first argues that the Prescription Information Law is not subject to the First Amendment because it does not regulate speech. Alternatively, she argues that the law is a commercial speech restriction that is subject only to intermediate scrutiny. She then claims that the law readily passes the intermediate scrutiny test because it has been carefully crafted to directly serve the State's substantial

interests in protecting prescriber privacy, promoting public health, and controlling health care costs.⁹

I resolve this dispute by examining each of the Attorney General's arguments in turn. As I explain below, I ultimately conclude that the Prescription Information Law violates the First Amendment because it improperly restricts commercial speech.

A. *Does the Challenged Statute Restrict "Speech"?*

The Attorney General first argues that the Prescription Information Law does not restrict "speech" protected by the First Amendment. This argument takes two forms, neither of which has merit. First, she argues that the First Amendment does not apply to the Prescription Information Law because it

⁹ The Attorney General also contends that plaintiffs lack standing to sue because they are not subject to prosecution under the Prescription Information Law. I am not persuaded by this argument. First, it is at least arguable that plaintiffs could be prosecuted under the law because they acquire prescriber-identifiable data and resell it for commercial purposes and thus are "other similar entit[ies]" that are subject to prosecution under the law. In any event, they are plainly subject to prosecution as conspirators if they conspire with covered entities to violate the law. See N.H.Rev.Stat. Ann. § 629:3 (1999). More fundamentally, it is undisputed that plaintiffs have incurred substantial costs to comply with the law and face revenue losses if they are unable to acquire and resell prescriber-identifiable data. This kind of economic injury is sufficient to give them standing to sue. See *Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 286-87, 117 S.Ct. 811, 136 L.Ed.2d 761 (1997).

targets unprotected factual information rather than constitutionally protected speech. This argument is contradicted by Supreme Court precedent. *See, e.g., Fla. Star v. B.J.F.*, 491 U.S. 524, 540-41, 109 S.Ct. 2603, 105 L.Ed.2d 443 (1989) (rape victim's name); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976) (drug prices); *see also Miller v. California*, 413 U.S. 15, 34, 93 S.Ct. 2607, 37 L.Ed.2d 419 (1973) (stating that First Amendment protects speech that has scientific value). As the Second Circuit has acknowledged in discussing this precedent, "[e]ven dry information, devoid of advocacy, political relevance, or artistic expression, has been accorded First Amendment protection." *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446-47 (2d Cir.2001) (citing Supreme Court cases). Here, the challenged law restricts the transmission of truthful information concerning the prescribing practices of New Hampshire's health care providers. It is not exempt from First Amendment review merely because it targets factual information rather than viewpoints, beliefs, emotions, or other types of expression.

The Attorney General next argues that the Prescription Information Law does not restrict speech because it regulates "uses" of prescriber-identifiable information rather than the disclosure of such information. This argument is based on the mistaken premise that the law restricts only the uses to which prescriber-identifiable data may be put. In fact, the

challenged statute provides that prescriber-identifiable information "shall not be licensed, *transferred*, used or sold" for a prohibited purpose. N.H.Rev.Stat. Ann. § 318:47-f (emphasis added). A transfer of information to a third party is a form of disclosure. The law is thus a speech restriction because it limits both the use and disclosure of prescriber-identifiable data for commercial purposes. *Bartnicki v. Vopper*, 532 U.S. 514, 526-27, 121 S.Ct. 1753, 149 L.Ed.2d 787 (2001) (a "prohibition against disclosures is fairly characterized as a regulation of pure speech.").

The Attorney General's argument would fail even if the Prescription Information Law did not directly restrict the disclosure of prescriber-identifiable data. A law is not automatically exempt from the First Amendment merely because it regulates protected speech only indirectly. See, e.g., *Minneapolis Star & Tribune Co. v. Minn. Comm'r of Revenue*, 460 U.S. 575, 585, 103 S.Ct. 1365, 75 L.Ed.2d 295 (1983) (special tax on ink and paper used in production of a publication violates First Amendment). Here, the challenged Law restricts speech by preventing pharmaceutical companies from using prescriber-identifiable information both to identify a specific audience for their marketing efforts and to refine their marketing messages.¹⁰ Such laws are subject to

¹⁰ Although a plaintiff ordinarily cannot base a claim to relief on the rights of third parties, the Supreme Court has recognized an exception to the general rule when vendors who have suffered their own injuries also assert the rights of their

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First Amendment scrutiny because they affect both the speaker's ability to communicate with his intended audience and the audience's right to receive information. *U.S. West, Inc. v. Fed. Comm'n Comm'n*, 182 F.3d 1224, 1232 (10th Cir.1999) (regulations restricting use of customer information for marketing purposes regulate speech protected by the First Amendment). Accordingly, I reject the Attorney General's argument that the Prescription Information Law is not subject to the First Amendment.

B. What Level of Scrutiny Applies?

Having determined that the Prescription Information Law restricts speech, I must next decide whether to apply strict scrutiny or intermediate scrutiny in evaluating plaintiffs' First Amendment claim. Plaintiffs argue that strict scrutiny applies because the Prescription Information Law is a content-based restriction on non-commercial speech. The Attorney General responds by claiming that intermediate scrutiny is the appropriate standard of review because the challenged provision regulates commercial speech. I agree with the Attorney General.

Commercial speech regulations ordinarily are subject to intermediate scrutiny. *Cent. Hudson Gas &*

customers. See *Craig v. Boren*, 429 U.S. 190, 194-95, 97 S.Ct. 451, 50 L.Ed.2d 397 (1976). This exception applies here and permits plaintiffs to assert the First Amendment interests of their pharmaceutical company customers.

Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 564, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980). The case law, however, is unclear as to how commercial speech is defined. Sometimes it is deemed to be speech "related solely to the economic interests of the speaker and its audience." *Id.* at 561, 100 S.Ct. 2343. Other times it is defined more narrowly to encompass only speech that "propose[s] a commercial transaction." *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473-74, 109 S.Ct. 3028, 106 L.Ed.2d 388 (1989); see also Eugene Volokh, *Freedom of Speech and Information Privacy: The Troubling Implications Of A Right To Stop People From Speaking About You*, 52 STAN. L. REV. 1049, 1082-83 (2000).

Plaintiffs contend that the Supreme Court repudiated *Central Hudson's* broader definition of commercial speech in *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 423-24, 113 S.Ct. 1505, 123 L.Ed.2d 99 (1993). I reject this argument both because the Supreme Court's holding in *Discovery* is more limited than plaintiffs suggest, *id.* at 424, 428, 113 S.Ct. 1505, and because the First Circuit continues to apply *Central Hudson's* broader definition. See *Pharm. Care Mngt. Ass'n v. Rowe*, 429 F.3d 294, 309 (1st Cir.2005) (applying test in case that presented a "close question" whether speech at issue was commercial); *El Dia, Inc. v. P.R. Dep't of Consumer Affairs*, 413 F.3d 110, 115 (1st Cir.2005). Accordingly, I will evaluate the Prescription Information Law by using the definition of commercial speech described in *Central Hudson*.

The Prescription Information Law plainly qualifies as commercial speech under *Central Hudson*. In understanding why this is so, it is important to bear in mind that the challenged law only restricts the transmission or use of prescriber-identifiable information for certain commercial purposes. It does not prevent anyone from transmitting or using the information for law enforcement purposes, research purposes, educational purposes, compliance review purposes, or for any non-commercial purpose. In short, the law is a commercial speech restriction under *Central Hudson* because it restricts only speech that is "solely in the individual interest of the speaker and its specific business audience," *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 762, 105 S.Ct. 2939, 86 L.Ed.2d 593 (1985) (plurality opinion); see also *Trans Union Corp. v. Fed. Trade Comm'n*, 245 F.3d 809, 818 (D.C.Cir.2001) (applying intermediate scrutiny to ban on sale of targeted marketing lists).

I would reach the same conclusion even under the narrower definition of commercial speech used in *Fox*. Although the data that the Prescription Information Law directly restricts does not itself propose a commercial transaction, the law's primary purpose is to affect commercial transactions by making it more difficult for pharmaceutical companies to convince health care providers to prescribe brand-name drugs when less expensive and equally effective alternatives are available. The law is thus squarely aimed at speech that proposes a commercial transaction even

though it does not explicitly bar such speech. Because the only use of prescriber-identifiable data that the law prohibits is its use in connection with speech that proposes a commercial activity, the Prescription Information Law qualifies as a commercial speech restriction even under *Fox's* more narrow definition of the term.¹¹

C. Does the Statute Pass Intermediate Scrutiny?

1. The Intermediate Scrutiny Test

Truthful commercial speech that does not promote unlawful activity can be limited under *Central Hudson* only if it "(1) is in support of a substantial government interest, (2) 'directly advances the government interest asserted,' and (3) 'is not more extensive than is necessary to serve that interest.'" *El Dia*, 413 F.3d at 113 (quoting *Cent. Hudson*, 447 U.S. at

¹¹ I also reject plaintiffs' alternative argument that strict scrutiny is required because the Prescription Information Law is a content-based commercial speech restriction. "[G]iven the Supreme Court's commercial speech doctrine, which creates a category of speech defined by the content but afforded only qualified protection, the fact that a restriction is content-based cannot alone trigger strict scrutiny." *Trans Union Corp. v. Fed. Trade Comm'n*, 267 F.3d at 1141-42 (citing *City of Cincinnati*, 507 U.S. at 410, 113 S.Ct. 1505); see also *Consol. Cigar Corp. v. Reilly*, 218 F.3d 30, 41-43 (1st Cir.2000) (applying intermediate scrutiny to regulation of tobacco-related advertising even though the restriction was content-based), *aff'd in pertinent part*, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 121 S.Ct. 2404, 150 L.Ed.2d 532 (2001).

566, 100 S.Ct. 2343). The party seeking to uphold a commercial speech restriction bears the burden of proof with respect to all three elements.¹² *Thompson*

¹² The Attorney General contends that I must defer to the New Hampshire legislature's predictive judgments in holding her to this burden. When a quality record establishes that the legislature conducted an extensive investigation, acquired considerable expertise in the regulated area, and incorporated express findings into the approved statute, a court must accord substantial deference to the legislature's predictive judgments, even when legislation affects protected speech. See *Turner Broad. Sys., Inc. v. Fed. Commc'n Comm*, 520 U.S. 180, 186, 117 S.Ct. 1174, 137 L.Ed.2d 369 (1997) ("Turner II"). In contrast, if the legislative record lacks this kind of support, considerably less deference is warranted. See *Sable Commc'ns of Cal. v. Fed. Commc'n Comm'n*, 492 U.S. 115, 129-30, 109 S.Ct. 2829, 106 L.Ed.2d 93 (1989) (no deference where legislative record "contains no evidence as to how effective or ineffective the . . . regulations were or might prove to be"); *Landmark Commc'ns, Inc. v. Virginia*, 435 U.S. 829, 843, 98 S.Ct. 1535, 56 L.Ed.2d 1 (1978) (no deference where statute was devoid of "actual facts" and contained only "legislative declaration[s]").

Here, the New Hampshire legislature determined that the Prescription Information Law was necessary to protect prescriber privacy and save money for the State, consumers, and businesses. There is nothing in the record, however, to support a conclusion that the legislature had established expertise in the regulation of prescriber-identifiable data. Moreover, it acted quickly after the bill was introduced, received hearing testimony by numerous individuals who had yet to review proposed amendments, made no express findings either on the record or incorporated into the statute, failed to discuss alternative measures that would not restrict speech, and cited no evidence as to how effective the restriction might prove to be. Principles of federalism and separation of powers counsel respect for the New Hampshire legislature at all times, including here. In light of the particulars of this case, however, I am not free to simply

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v. W States Med. Ctr., 535 U.S. 357, 373, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002).

To satisfy the first two elements of the *Central Hudson* test, the party defending a commercial speech restriction must identify a substantial governmental interest that underlies the restriction. *Id.* at 367, 122 S.Ct. 1497. It then "must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Edenfield v. Fane*, 507 U.S. 761, 770-71, 113 S.Ct. 1792, 123 L.Ed.2d 543 (1993). A restriction that provides "only ineffective or remote support for the government's purpose" will not be sustained. *Id.* at 770, 113 S.Ct. 1792 (quoting *Cent. Hudson*, 447 U.S. at 564, 100 S.Ct. 2343). Although empirical data supporting a commercial speech restriction need not be "accompanied by a surfeit of background information," *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 628, 115 S.Ct. 2371, 132 L.Ed.2d 541 (1995), "mere speculation or conjecture" that a speech restriction will cure a purported harm is insufficient to justify it. *Edenfield*, 507 U.S. at 770, 113 S.Ct. 1792.

The test's third element focuses on the fit between the challenged speech restriction and the governmental interest it is designed to serve. Absolute precision

endorse its actions without careful analysis. See *Scble*, 492 U.S. at 129, 109 S.Ct. 2829 (quoting *Landmark*, 435 U.S. at 843, 98 S.Ct. 1535) ("Deference to a legislative finding cannot limit judicial inquiry when First Amendment rights are at stake.").

is not required. Instead, a restriction will suffice if the fit is both "reasonable" and "in proportion to the interest served." *Fox*, 492 U.S. at 480, 109 S.Ct. 3028 (quoting *In re R.M.J.*, 455 U.S. 191, 203, 102 S.Ct. 929, 71 L.Ed.2d 64 (1982)). Nevertheless, "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Thompson*, 535 U.S. at 371, 122 S.Ct. 1497.

2. Application

The Attorney General contends that the Prescription Information Law is a permissible commercial speech restriction because it is narrowly drawn and directly advances the State's substantial interests in protecting prescriber privacy, promoting public health, and containing health care costs. Plaintiffs challenge the Attorney General's contention that the State has a substantial interest in protecting prescriber privacy. They also argue that the law cannot be justified as either a public health law or a cost containment measure because the evidence in the record fails to prove that the law will directly serve either interest. Finally, they argue that the law is invalid even if it is effective because its purposes could be achieved as well or better through alternatives that do not restrict protected speech. I address each argument in turn.

**a. Is Protecting Prescriber Privacy
a Substantial Governmental Interest?**

In arguing that the State has a substantial interest in protecting prescriber privacy, the Attorney General makes a very narrow claim. She does not argue that prescriber-identifiable data is personal or private information that the State has a substantial interest in helping health care providers shield from public view.¹³ Nor does she contend that the data is

¹³ It is not surprising that the Attorney General does not seek to defend the Prescription Information Law as an information privacy measure. First, the challenged provisions target professional information rather than personal information. This distinction is important because most information privacy laws protect the privacy of personal information. *See, e.g.,* Health Insurance Portability and Accountability Act of 1996, Pub.L. No. 104-191, 110 Stat. 1936 (codified in scattered sections of 18 U.S.C., 26 U.S.C., 29 U.S.C., and 42 U.S.C.) (patient medical information); Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq. (2000) (credit reporting information); Family Educational Rights and Privacy Act of 1974, 20 U.S.C. § 1232g (2000 & Supp. III 2003) (educational information); Video Privacy Protection Act of 1988, 18 U.S.C. § 2710 (2000) (video rental information); Cable Communications Policy Act of 1984, Pub.L. No. 98-549, 98 Stat. 2779 (subscriber information). Any argument that the State's interest in protecting business information is equivalent to its interest in protecting personal information would require a substantial extension of existing precedent. *See Vega-Rodriguez v. P.R. Tel. Co.*, 110 F.3d 174, 183 (1st Cir.1997) (Fourteenth Amendment right to information privacy "has not extended beyond prohibiting profligate disclosure of medical, financial, and other intimately personal data"). Second, health care providers cannot credibly claim that they have a reasonable expectation that their prescribing practices will remain private

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intellectual property that may be protected from public disclosure as trade secret information. Instead, she claims only that the law serves the State's substantial interest in protecting prescriber privacy by "limiting unwarranted intrusions into the decision-making process of prescribing physicians." Def.'s Trial Memorandum at 20 (Doc. No. 66).

The case law that the Attorney General relies on to support the State's claimed interest in protecting the decision-making process of prescribers recognizes that the State has a substantial interest in regulating speech that: (i) intrudes upon "the well being, tranquility, and privacy of the home," *Carey v. Brown*, 447 U.S. 455, 471, 100 S.Ct. 2286, 65 L.Ed.2d 263 (1980); (ii) is "pressed with such frequency or vehemence as to intimidate, vex, or harass the recipient," *Edenfield*, 507 U.S. at 769, 113 S.Ct. 1792; or (iii) involves "willful or knowing affront to or invasion of the

because prescriber-identifiable data is routinely disclosed to patients, pharmacies, insurance companies, medical review committees, and government agencies. In other words, because health care providers work in a "closely-regulated" industry, they have at best a diminished expectation of privacy with respect to their prescribing practices. *New York v. Burger*, 482 U.S. 691, 702, 107 S.Ct. 2636, 96 L.Ed.2d 601 (1987) (operators of closely regulated business have diminished expectation of privacy). Finally, it is difficult to see how the law's restriction on the transmission and use of prescriber-identifiable data can be successfully characterized as an information privacy measure because, as the Attorney General concedes, the law does not "attempt to keep prescriber-identifiable data secret or entirely private." Def.'s Trial Memorandum at 20 n. 10 (Doc. No. 66).

tranquility of bereaved or injured individuals," *Fla. Bar*, 515 U.S. at 630, 115 S.Ct. 2371. The present case is far different, however, from other cases in which the state's interest in protecting citizens from improper commercial solicitation has been recognized as substantial. First, although the Attorney General asserts that pharmaceutical companies use prescriber-identifiable data to "pressure" health care providers, she did not even attempt to prove at trial that they use the data to improperly coerce or harass health care providers.¹⁴ Second, it is obvious that the current case does not involve solicitations that invade the tranquility of the home or that target vulnerable victims. Finally, although the Attorney General asserts that prescriber-identifiable data is used to

¹⁴ The Prescription Information Law's legislative history includes two references that arguably support the view that prescriber-identifiable data can be used to coerce health care providers. The first consists of testimony from a nurse practitioner who was told by a sales representative that her once-a-week deliveries of free coffee and donuts would be discontinued unless the practitioner wrote more prescriptions. S. Comm. Hearing on H.B. 1346 at 33, Attachment 15. The second is a newspaper article that describes an email in which a pharmaceutical sales manager exhorted her sales staff to hold their doctors accountable for the samples, gifts, meals, and other inducements they had received. *Id.* at 27, Attachment 13 (quoting *Harris & Pear, supra*). The Attorney General did not follow up on this evidence at trial, and those witnesses who discussed the issue of coercion were not aware of any instances in which health care providers were coerced into writing prescriptions. Thus, I do not find any credible evidence in the record that supports the notion that pharmaceutical companies are routinely using prescriber-identifiable data to coerce health care providers.

intrude upon the doctor-patient relationship, she does not claim that the data is being exploited to compromise patient privacy. Instead, she argues only that pharmaceutical companies are using the data to help persuade doctors to make inadvisable prescribing decisions. In short, what the Attorney General claims as a distinct interest in protecting prescriber privacy is nothing more than a restatement of her contentions that the law can be justified because it prevents pharmaceutical companies from using prescriber-identifiable data in ways that undermine public health and increase health care costs. Accordingly, I reject the Attorney General's argument that the law can be justified on the distinct basis that it promotes prescriber privacy.

b. Does the Prescription Information Law Directly Advance the State's Interests in Promoting Public Health and Containing Health Care Costs?

The Attorney General contends that the Prescription Information Law is a valid commercial speech restriction because it prevents pharmaceutical companies from using prescriber-identifiable data in ways that undermine public health and increase health care costs. The chain of reasoning that leads to this conclusion begins with the major premise that prescriber-identifiable data allows pharmaceutical companies to target health care providers for marketing and tailor marketing messages in ways that make

detailing more persuasive. Next, it assumes that because prescriber-identifiable data makes detailing more persuasive, it inevitably leads to more prescriptions for brand-name drugs when compared with generic alternatives because only branded drugs are detailed. Finally, it assumes that any increase in the number of prescriptions written for brand-name drugs when compared to generic alternatives harms the public health and increases health care costs because branded drugs often turn out to be more harmful than generic alternatives and almost always are more expensive. Accordingly, a ban on the use of prescriber-identifiable data for marketing purposes promotes public health and contains health care costs by prohibiting pharmaceutical companies from using prescriber-identifiable data to promote the sale of brand-name drugs.

I am unpersuaded by the Attorney General's ultimate conclusion that the Prescription Information Law directly promotes public health and contains health care costs even though I accept her major premise that pharmaceutical companies use prescriber-identifiable data to make detailing more persuasive. Any general claim that the public health is undermined when the effectiveness of detailing for brand-name drugs is increased depends upon the counterintuitive and unproven proposition that, on balance, brand-name drugs are more injurious to the public health than generic alternatives. Moreover, although the Attorney General specifically claims that the State is entitled to ban the use of prescriber-identifiable data

because it is being used to target "early adopters" for the marketing of dangerous new drugs, her argument is unpersuasive because the record does not establish either that early adopters are more likely to be influenced by detailing than other health care providers or that new drugs are generally more injurious to the public health than existing medications. Accordingly, the Attorney General has failed to prove that the Prescription Information Law directly promotes public health.

I am also unconvinced by the Attorney General's argument that the Prescription Information Law directly promotes the State's interest in containing health care costs. The Attorney General appears to assume that any health care cost savings that will result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care. However, this proposition is far from self-evident. Non-bioequivalent generic drugs are not always as effective as brand-name alternatives.¹⁶ Moreover, even in cases where non-bioequivalent generic drugs will work as well or better than a brand-name alternative for most patients, there may be some patients who will benefit by taking the

¹⁶ I refer only to non-bioequivalent generic drugs because the parties agree that a ban on the use of prescriber-identifiable data will not affect a prescriber's choice between a brand-name drug and a bioequivalent generic alternative. This is because, as the Attorney General acknowledges, pharmaceutical companies generally stop detailing branded drugs when bioequivalent generic drugs become available.

branded medication. Yet, a ban on the use of prescriber-identifiable data affects both helpful and harmful brand-name prescribing practices in the same way. Because the Attorney General has failed to prove that any reductions in health care costs that may result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care, I am unable to endorse her argument that the Prescription Information Law can be justified as a cost containment measure.

The Attorney General's argument also suffers from a fundamental flaw that would prevent me from endorsing it even if the assumptions on which it is based were true. Although the Attorney General complains that pharmaceutical companies use prescriber-identifiable data to "manipulate" health care providers, it is important to understand that she does not assert that the data is being used to propagate false or misleading marketing messages. Instead, she argues that pharmaceutical companies manipulate health care providers by using prescriber-identifiable data to enhance the effectiveness of highly persuasive but truthful commercial speech. As the Supreme Court has recently explained, however, "[w]e have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Thompson*, 535 U.S. at 374, 122 S.Ct. 1497; see also, *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503, 116 S.Ct. 1495, 134

L.Ed.2d 711 (1996) (“[B]ans against truthful, non-misleading commercial speech . . . usually rest solely on the offensive assumption that the public will respond ‘irrationally’ to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.”) (citation omitted); *Va. State Bd. of Pharmacy*, 425 U.S. at 770, 96 S.Ct. 1817. Health care providers are highly trained professionals who are committed to working in the public interest. They certainly are more able than the general public to evaluate truthful pharmaceutical marketing messages. Accordingly, the State simply does not have a substantial interest in shielding them from sales techniques that enhance the effectiveness of truthful and non-misleading marketing information. Instead, if the State is concerned that truthful detailing is causing health care providers to make inadvisable prescribing decisions, “the remedy to be applied is more speech, not enforced silence.” *Whitney v. California*, 274 U.S. 357, 377, 47 S.Ct. 641, 71 L.Ed. 1095 (1927) (Brandeis, J. concurring).

c. Is the Prescription Information Law More Extensive Than Necessary to Serve the State's Substantial Interests?

Even the harshest critics of pharmaceutical detailing acknowledge that it is sometimes used in ways that benefit public health.¹⁶ Not all new drugs are harmful and generic drugs are not always as effective for all patients as brand-name alternatives. When new drugs work as advertised and branded drugs are superior to non-bioequivalent generic alternatives, detailing serves the state's interest in public health by promoting efficacious treatments. The Prescription Information Law, however, does not discriminate between beneficial detailing and harmful detailing. Instead, it imposes a sweeping ban on the use of prescriber-identifiable information to enhance the effectiveness and efficiency of all detailing. Because this ban restricts commercial speech, it cannot be sustained unless it is no more extensive

¹⁶ The Attorney General has presented testimony, a written declaration, and published reports of numerous studies conducted by Dr. Jerry Avorn, Professor of Medicine at Harvard Medical School and Chief of the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital. Dr. Avorn is a renowned expert on the effects of pharmaceutical marketing on drug utilization and prescribing behaviors. Although Dr. Avorn is critical of detailing, even he is quick to acknowledge that it has beneficial uses and should not be banned. (Trial Tr. vol. 3 Afternoon Session, 68:13-25, 85:19-23, 87:17-25, Jan. 31, 2007 (Doc. No. 114)).

than necessary to serve the State's claimed interests in promoting public health and containing health care costs.

The record in this case demonstrates that there are a number of ways in which the State can address the concerns that underlie the Prescription Information Law without restricting protected speech. First, if legislators are concerned that pharmaceutical companies are improperly using samples, gifts, meals, and other inducements to promote inadvisable prescribing practices, they can address this perceived problem by following other states that have adopted laws that limit such practices. *See, e.g.*, Minn.Stat. Ann. § 151.461 (2007); Cal. Health and Safety Code § 119402(d)(1) (2007).

Second, if legislators fear that pharmaceutical detailing is simply too effective to go unrebuted, they can require the State to enter the intellectual marketplace in several different ways with competing information that will help health care providers balance and place in context the sales messages that detailers deliver. Among other things, they can require the State to prepare and distribute "best practice" guidelines that educate health care providers as to both the health and cost implications of their prescribing decisions; require the State to develop counter-detailing programs that make health care providers aware of the cost implications of their prescribing decisions, *see, e.g.*, W. Va.Code Ann. § 5-16C-9(5) (2006) (authorizing state to develop counter-detailing programs); or they can require health care

providers to regularly participate in continuing medical education programs that are specifically designed to provide practitioners with the best available information concerning the advantages and disadvantages of prescribing generic drugs rather than brand-name drugs.

Finally, if legislators are concerned that pharmaceutical companies are using prescriber-identifiable data to drive up Medicaid drug costs, they can address the issue directly by properly implementing a Medicaid Pharmacy Program that takes into account the cost-effectiveness of brand-name drugs when compared with non-bioequivalent generic alternatives. New Hampshire's Medicaid Pharmacy Benefit Program requires health care providers to obtain authorization from state officials before prescribing certain drugs for Medicaid patients. *See generally*, 2004 N.H. Laws, ch. 188 (authorizing the New Hampshire Department of Health and Human Services to establish a preferred drug list and a prior authorization process). The State has also adopted regulations that both authorize the State to take cost considerations into account when deciding which drugs should be subjected to the prior authorization requirement, N.H. Admin. Rules, HeW570.06(F)(3), and permit the State to reject requests to prescribe drugs that are subject to prior authorization, N.H. Admin. Rules, HE-W570.06(I)-(P). Accordingly, the State can prevent unnecessary expenditures on brand-name drugs simply by subjecting such drugs to

prior authorization and rejecting requests to prescribe them when they are not medically necessary.

Although the parties have not briefed the issue, it is likely that New Hampshire's current Pharmacy Benefit Program conflicts with federal Medicaid law because it both allows state officials to take a drug's comparative cost into account when deciding whether to subject it to prior authorization and permits the State to reject requests to prescribe drugs subject to prior authorization. See *Pharm. Research & Mfrs. of Am. v. Meadows*, 304 F.3d 1197, 1201-02 (11th Cir.2002) (construing 42 U.S.C. § 1396r-8). Even if New Hampshire's current program violates federal law, however, legislators could amend the program to both bring it into compliance with federal law and require prescribers to consider the cost implications of prescribing drugs that are subject to prior authorization. One way that this could be done would be to eliminate the State's power to deny prescription requests for non-preferred drugs and replace it with a requirement that health care providers consult with a state pharmacist before prescribing such drugs. Florida has a law that requires consultation, and it has both withstood a court challenge and proved to be highly effective in persuading health care providers to change their prescribing practices. *Id.* at 1198, 1205 (discussing Fla. Stat. § 409.91195, 409.912).

Dynacirc and Verapamil, two calcium channel blockers that Representative Price cited in support of the Prescription Information Law, illustrate how the State's Pharmacy Benefit Program could be used to

limit unnecessary prescriptions for brand-name drugs. Both drugs are currently treated as preferred drugs under the program, *available at* <http://www.dhhs.state.nh.us/DHHS/MEDICAIDPROGRAM/LIBRARY/Policy-Guideline/preferred-drug.htm> (follow "NH Medicaid Preferred Drug List-PDL" hyperlink). Thus, both drugs may currently be prescribed without prior authorization. If Dynacirc is substantially more expensive than Verapamil but no more effective for most patients, as Representative Price implied during the legislative hearing on the Prescription Information Law, the State could substantially limit unnecessary prescriptions for Dynacirc under its existing program simply by making it a non-preferred drug and denying unwarranted requests for prior authorization. If the State instead adopted a program such as the one used in Florida, it could require health care providers to consult with a state pharmacist before prescribing Dynacirc for Medicaid patients. Under either approach, the State could significantly reduce Medicaid spending on non-preferred drugs without restricting constitutionally protected speech.

III. CONCLUSION

The Prescription Information Law attempts to address important public policy concerns. Ordinarily, states should be given wide latitude to choose among rational alternatives when they act to benefit the public interest. However, when states adopt speech restrictions as their method, courts must subject their efforts to closer scrutiny. Because the Prescription

Information Law restricts constitutionally protected speech without directly serving the State's substantial interests and because alternatives exist that would achieve the State's interests as well or better without restricting speech, the law cannot be enforced to the extent that it purports to restrict the transfer or use of prescriber-identifiable data. Plaintiffs' request for declaratory relief and a permanent injunction are granted.

SO ORDERED.

**United States Court of Appeals
For the First Circuit**

No. 07-1945

IMS HEALTH, INCORPORATED,
a Delaware Corporation; VERISPAN, LLC,
a Delaware Limited Liability Company

Plaintiffs-Appellees

v.

KELLY A. AYOTTE, Attorney General
for the State of New Hampshire

Defendant-Appellant

Before

Lynch, *Chief Judge*,
Torruella, Selya, Siler,* Bouldin,
Lipez and Howard,**
Circuit Judges.

ORDER OF COURT

Entered: January 14, 2009

* Judge Eugene E. Siler of the U.S. Court of Appeals for the Sixth Circuit sitting by designation.

** Judge Jeffrey R. Howard is recused and did not participate in the consideration of this matter.

The petition for rehearing have been denied by the panel of judges who decided the case, and the petition for rehearing en banc having been submitted to the active judges of this court and a majority of the judges not having voted that the case be heard en banc, it is ordered that the petition for rehearing and the petition for rehearing en banc be *denied*.

The motion to file an amicus brief in support of the petition for rehearing/rehearing en banc by Manufacturers of America and Pharmaceutical Research is *denied as moot*.

The motion to file an amicus brief in support of the petition for rehearing/rehearing en banc by American Business Media, First American Core Logic, Inc. National Association of Professional Background Screeners and Reed Elsevier, Inc. is *denied as moot*.

By the Court:

/s/ Richard Cushing Donovan, Clerk

cc: Patricia Acosta
Mark A. Ash
James P. Bassett
Thomas R. Julin
Michelle R. Milberg
Jeffrey C. Spear
Richard W. Head
Laura E. B. Lombardi
David A. Rienzo
Craig S. Donais
Daniel J. Popeo
Richard A. Samp

Don L. Bell
Garry R. Lane
William S. Bernstein
Terri D. Keville
David J. Shulock
John Kamp
Walter L. Maroney
Andrew M. Miller
Bert W. Rein
Joshua Scott Turner
Stacy J. Canan
Sean Fiil-Flynn
Bruce Vignery
Harold C. Becker
Katherine Webster
Donald B. Ayer
Stephen J. Judge
Charles R. A. Morse
Melissa Ngo
Marc S. Rotenberg

2006 New Hampshire Laws Ch. 328 (H.B. 1346)

**NEW HAMPSHIRE 2006 SESSION LAWS
2006 REGULAR SESSION**

Additions are indicated by **Text**; deletions by
~~Text~~. Changes in tables are made
but not highlighted.

Ch. 328
H.B. 1346

**PHARMACISTS AND PHARMACIES –
PRESCRIPTION INFORMATION –
CONFIDENTIALITY**

AN ACT requiring certain persons to keep
the contents of prescriptions confidential.

Be it Enacted by the Senate and House of
Representatives in General Court convened:

328:1 New Sections; Pharmacists and Pharmacies; Prescription Information to be Kept Confidential. Amend RSA 318 by inserting after section 47-e the following new sections:

318:47-f Prescription Information to be Kept Confidential. Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management;

utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force. Nothing in this section shall prohibit the dispensing of prescription medications to a patient or to the patient's authorized representative; the transmission of prescription information between an authorized prescriber and a licensed pharmacy; the transfer of prescription information between licensed pharmacies; the transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred; care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy or other information about the drug being dispensed, treatment options, or clinical trials. Nothing in this section shall prohibit the collection, use, transfer or sale of patient and prescriber de-identified data by zip code, geographic region, or medical specialty for commercial purposes. In addition to other appropriate remedies under this chapter, a violation of this section is an unfair or deceptive act or practice within the meaning of RSA 358-A:2. Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this section.

318:47-g Patient Assistance Program.

I. Following the close of each calendar year, any clearinghouse that provides information to New Hampshire residents about pharmaceutical manufacturers' patient assistance programs shall, to the extent that the clearinghouse collects such information, provide aggregate information to the commissioner of the department of health and human services relative to either:

(a) The number of people in New Hampshire who may qualify for any manufacturer or government program during the calendar year; or

(b) The number of patients served during the calendar year.

II. An individual company may provide additional information about the individual company's patient assistance program; however, the commissioner shall combine all information from all sources, including individual companies and the clearinghouse, and shall report only aggregate information to the public.

328:2 New Paragraph; Controlled Drug Act; Prescription Information to be Kept Confidential. Amend RSA 318-B:12 by inserting after paragraph III the following new paragraph:

IV. Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager,

insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise required by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force. Nothing in this paragraph shall prohibit the dispensing of prescription medications to a patient or to the patient's authorized representative; the transmission of prescription information between an authorized prescriber and a licensed pharmacy; the transfer of prescription information between licensed pharmacies; the transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred; care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy or other information about the drug being dispensed, treatment options, or clinical trials. Nothing in this section shall prohibit the collection, use, transfer, or sale of patient and prescriber de-identified data by zip code, geographic region, or medical specialty for commercial purposes. In addition to other

appropriate remedies under this chapter, a violation of this paragraph is an unfair or deceptive act or practice within the meaning of RSA 358-A:2. Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this paragraph.

328:3 Effective Date. This act shall take effect upon its passage.

(Approved: June 30, 2006)

(Effective: June 30, 2006)

**Title XXX New Hampshire
Occupations and Professions**

**Chapter 318-B
Controlled Drug Act**

Section 318-B:26

318-B:26 Penalties. -

I. Any person who manufactures, sells, prescribes, administers, or transports or possesses with intent to sell, dispense, or compound any controlled drug, controlled drug analog or any preparation containing a controlled drug, except as authorized in this chapter; or manufactures, sells, or transports or possesses with intent to sell, dispense, compound, package or repackage (1) any substance which he represents to be a controlled drug, or controlled drug analog, or (2) any preparation containing a substance which he represents to be a controlled drug, or controlled drug analog, shall be sentenced as follows, except as otherwise provided in this section:

(a) In the case of a violation involving any of the following, a person shall be sentenced to a maximum term of imprisonment of not more than 30 years, a fine of not more than \$500,000, or both. If any person commits such a violation after one or more prior offenses as defined in RSA 318-B:27, such person may be sentenced to a maximum term of life imprisonment, a fine of not more than \$500,000, or both:

(1) Five ounces or more of a mixture or substance containing any of the following, including any adulterants or dilutants:

(A) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; or

(B) Cocaine other than crack cocaine, its salts, optical and geometric isomers, and salts of isomers; or

(C) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(2) Lysergic acid diethylamide, or its analog, in a quantity of 100 milligrams or more including any adulterants or dilutants, or phencyclidine (PCP), or its analog, in a quantity of 10 grams or more including any adulterants or dilutants.

(3) Heroin or its analog or crack cocaine in a quantity of 5 grams or more, including any adulterants or dilutants.

(4) Methamphetamine or its analog, in a quantity of 5 ounces or more, including adulterants or dilutants.

(b) In the case of a violation involving any of the following, a person may be sentenced to a maximum term of imprisonment of not more than 20 years, a fine of not more than \$300,000, or both. If any person commits such a violation after one or

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more prior offenses as defined in RSA 318-B:27, such person may be sentenced to a term of imprisonment of not more than 40 years, a fine of not more than \$500,000, or both:

(1) A substance or mixture referred to in subparagraph I(a)(1) of this section, other than crack cocaine, in a quantity of 1/2 ounce or more, including any adulterants or dilutants;

(2) A substance classified in schedule I or II other than those specifically covered in this section, or the analog of any such substance, in a quantity of one ounce or more including any adulterants or dilutants;

(3) Lysergic acid diethylamide, or its analog, in a quantity of less than 100 milligrams including any adulterants or dilutants, or where the amount is undetermined, or phencyclidine (PCP) or its analog, in a quantity of less than 10 grams, including any adulterants or dilutants, or where the amount is undetermined;

(4) Heroin or its analog or crack cocaine in a quantity of one gram or more, including any adulterants or dilutants;

(5) Methamphetamine or its analog, in a quantity of one ounce or more including any adulterants or dilutants;

(6) Marijuana in a quantity of 5 pounds or more including any adulterants or dilutants, or

hashish in a quantity of one pound or more including any adulterants and dilutants;

(7) Flunitrazepam in a quantity of 500 milligrams or more.

(c) In the case of a violation involving any of the following, a person may be sentenced to a maximum term of imprisonment of not more than 7 years, a fine of not more than \$100,000, or both. If any person commits such a violation after one or more prior offenses as defined in RSA 318-B:27, such person may be sentenced to a maximum term of imprisonment of not more than 15 years, a fine of not more than \$200,000, or both:

(1) A substance or mixture referred to in subparagraph I(a)(1) of this section, other than crack cocaine, in a quantity less than 1/2 ounce including any adulterants or dilutants;

(2) A substance or mixture classified as a narcotic drug in schedule I or II other than those specifically covered in this section, or the analog of any such substance, in a quantity of less than one ounce including any adulterants or dilutants;

(3) Methamphetamine, or its analog in a quantity of less than one ounce including any adulterants or dilutants;

(4) Heroin or its analog or crack cocaine in a quantity of less than one gram, including any adulterants or dilutants;

(5) Marijuana in a quantity of one ounce or more including any adulterants or dilutants, or hashish in a quantity of 5 grams or more including any adulterants or dilutants;

(6) Flunitrazepam in a quantity of less than 500 milligrams;

(7) Any other controlled drug or its analog, other than those specifically covered in this section, classified in schedules I, II, III or IV.

(d) In the case of a violation involving any of the following, a person may be sentenced to a maximum term of imprisonment of not more than 3 years, a fine of not more than \$25,000, or both. If any person commits such a violation after one or more prior offenses as defined in RSA 318-B:27, such person may be sentenced to a maximum term of imprisonment of not more than 6 years, a fine of not more than \$50,000, or both:

(1) Marijuana in a quantity of less than one ounce including any adulterants or dilutants, or hashish in a quantity of less than 5 grams including any adulterants or dilutants;

(2) Any schedule V substance or its analog.

II. Any person who knowingly or purposely obtains, purchases, transports, or possesses actually or constructively, or has under his control, any controlled drug or controlled drug analog, or any preparation containing a controlled drug or controlled drug

analog, except as authorized in this chapter, shall be sentenced as follows, except as otherwise provided in this section:

(a) In the case of a controlled drug or its analog, classified in schedules I, II, III or IV, other than those specifically covered in this section, the person shall be guilty of a class B felony, except that notwithstanding the provisions of RSA 651:2, IV(a), a fine of not more than \$25,000 may be imposed. If any person commits such a violation after one or more prior offenses as defined in RSA 318-B:27, such person shall be guilty of a class A felony, except that notwithstanding the provisions of RSA 651:2, IV(a), a fine of up to \$50,000 may be imposed;

(b) In the case of a controlled drug or its analog classified in schedule V, the person shall be sentenced to a maximum term of imprisonment of not more than 3 years, a fine of not more than \$15,000, or both. If a person commits any such violation after one or more prior offenses as defined in RSA 318-B:27, such person shall be guilty of a class B felony, except that notwithstanding the provisions of RSA 651:2, IV(a), a fine of not more than \$25,000 may be imposed;

(c) In the case of more than 5 grams of hashish, the person shall be guilty of a misdemeanor, except that notwithstanding the provisions of RSA 651:2, IV(a), a fine of not more than \$5,000 may be imposed.

(d) In the case of marijuana, including any adulterants or dilutants, or 5 grams or less of hashish, the person shall be guilty of a class A misdemeanor.

III. A person shall be guilty of a misdemeanor who:

(a) Controls any premises or vehicle where he knows a controlled drug or its analog is illegally kept or deposited;

(b) Aids, assists or abets a person in his presence in the perpetration of a crime punishable under paragraph II of this section, knowing that such person is illegally in possession of a controlled drug or its analog.

(c) Manufactures with the intent to deliver, delivers or possesses with the intent to deliver any drug paraphernalia when such paraphernalia is knowingly manufactured, delivered or possessed for one or more of the uses set forth in RSA 318-B:2, II.

(d) Places an advertisement in violation of RSA 318-B:2, III.

III-a. [Repealed.]

IV. Any person who attempts or conspires to commit any offense defined in this chapter is punishable by imprisonment or a fine or both, which may not exceed the maximum punishment prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

V. Any person who violates this chapter by manufacturing, selling, prescribing, administering, dispensing, or possessing with intent to sell, dispense, or compound any controlled drug or its analog, in or on or within 1,000 feet of the real property comprising a public or private elementary, secondary, or secondary vocational-technical school, may be sentenced to a term of imprisonment or fine, or both, up to twice that otherwise authorized by this section. Except to the extent a greater minimum sentence is otherwise provided by this chapter, a sentence imposed under this paragraph shall include a mandatory minimum term of imprisonment of not less than one year. Neither the whole nor any part of the mandatory minimum sentence imposed under this paragraph shall be suspended or reduced.

VI. Except as otherwise provided in this paragraph, a person convicted under RSA 318-B:2, XII as a drug enterprise leader shall be sentenced to a mandatory minimum term of not less than 25 years and may be sentenced to a maximum term of not more than life imprisonment. The court may also impose a fine not to exceed \$500,000 or 5 times the street value of the controlled drug or controlled drug analog involved, whichever is greater. Upon conviction, the court shall impose the mandatory sentence unless the defendant has pleaded guilty pursuant to a negotiated agreement or, in cases resulting in trial, the defendant and the state have entered into a post-conviction agreement which provides for a lesser sentence. The negotiated plea or post-conviction

agreement may provide for a specified term of imprisonment within the range of ordinary or extended sentences authorized by law, a specified fine, or other disposition. In that event, the court at sentencing shall not impose a lesser term of imprisonment or fine than that expressly provided for under the terms of the plea or post-conviction agreement.

VII. Any person who violates RSA 318-B:2, XI may be sentenced to a maximum term of imprisonment of not more than 20 years, a fine of not more than \$300,000, or both. If any person commits such a violation after one or more prior offenses, as defined in RSA 318-B:27, such person may be sentenced to a term of imprisonment of not more than 40 years, a fine of not more than \$500,000, or both.

VIII. Any person who knowingly or purposely obtains or purchases (1) any substance which he represents to be a controlled drug or controlled drug analog, or (2) any preparation containing a substance which he represents to be a controlled drug or controlled drug analog, except as authorized in this chapter, shall be guilty of a misdemeanor. If any person commits such a violation after one or more prior offenses as defined in RSA 318-B:27, such person shall be guilty of a class B felony.

IX. Any person who manufactures, sells, or dispenses methamphetamine, lysergic acid, diethylamide phencyclidine (PCP) or any other controlled drug classified in schedules I or II, or any controlled drug analog thereof, in violation of RSA 318-B:2, I or

I-a, is strictly liable for a death which results from the injection, inhalation or ingestion of that substance, and may be sentenced to imprisonment for life or for such term as the court may order. For purposes of this section, the person's act of manufacturing, dispensing, or selling a substance is the cause of a death when:

(a) The injection, inhalation or ingestion of the substance is an antecedent but for which the death would not have occurred; and

(b) The death was not:

(1) Too remote in its occurrence as to have just bearing on the person's liability; or

(2) Too dependent upon conduct of another person which was unrelated to the injection, inhalation or ingestion of the substance or its effect, as to have a just bearing on the person's liability. It shall not be a defense to a prosecution under this section that the decedent contributed to his own death by his purposeful, knowing, reckless or negligent injection, inhalation or ingestion of the substance or by his consenting to the administration of the substance by another. Nothing in this section shall be construed to preclude or limit any prosecution for homicide. A conviction arising under this section shall not merge with a conviction of one as a drug enterprise leader or for any other offense defined in this chapter.

X. Any penalty imposed for violation of this chapter shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

XI. Any person who violates any provision of this chapter for which a penalty is not provided by paragraphs I through IX shall be guilty of a class B felony if a natural person, or guilty of a felony if any other person.

XII. The penalty categories set forth in this section based upon the weight of the drug involved are material elements of the offense; however, the culpability requirement shall not apply to that element of the offense.

XIII. Any person who violates any provision of this chapter shall be fined a minimum of \$350 for a first offense and \$500 for a second or subsequent offense.

Source. 1969, 421:1. 1970, 48:3. 1973, 528:204. 1977, 547:21. 1981, 114:2; 513:3, 4. 1988, 6:4. 1989, 195:2; 207:2-5. 1991, 364:2. 1993, 291:1. 1994, 186:3-11. 1998, 359:3, 4, eff. June 26, 1998. 2005, 177:52, eff. July 1, 2005. 2006, 241:2, eff. Jan. 1, 2007.

**Title XXX New Hampshire
Occupations and Professions**

**Chapter 318
Pharmacists and Pharmacies**

**Penalty
Chapter 318:55**

318:55 Fines and Imprisonment; Penalties. -

I. Any person violating the provisions of this chapter, except as otherwise provided, shall be guilty of a misdemeanor if a natural person, or guilty of a felony if any other person.

II. In addition to the penalties under paragraph I, the board may impose a civil penalty not to exceed \$5,000 per violation upon any person who willfully or repeatedly violates any provision of this chapter.

III. For any order issued in resolution of a disciplinary proceeding before the board, the board may require that any licensee, permittee, registrant, or certificate holder found guilty of a charge involving any drug law or rule to pay to the board a sum not to exceed the reasonable cost of investigation and prosecution of the proceeding. The sum shall not exceed \$5,000. The costs to be assessed shall be fixed by the board and any sums recovered shall be paid to the state treasurer for deposit in the general fund.

Source. 1909, 162:4. 1921, 122:30. PL 210:54. 1933, 61:2. RL 256:55. RSA 318:55. 1973, 528:203; 529:70. 1989, 258:4, eff. Jan. 1, 1990. 2007, 202:13, eff. Jan. 1, 2008.

Title LXII New Hampshire Criminal Code

Chapter 625 Preliminary

Section 625:9

625:9 Classification of Crimes. -

I. The provisions of this section govern the classification of every offense, whether defined within this code or by any other statute.

II. Every offense is either a felony, misdemeanor or violation.

(a) Felonies and misdemeanors are crimes.

(b) A violation does not constitute a crime and conviction of a violation shall not give rise to any disability or legal disadvantage based on conviction of a criminal offense.

III. A felony is murder or a crime so designated by statute within or outside this code or a crime defined by statute outside of this code where the maximum penalty provided is imprisonment in excess of one year; provided, however, that a crime defined by statute outside of this code is a felony when committed by a corporation or an unincorporated association if the maximum fine therein provided is more than \$200.

(a) Felonies other than murder are either class A felonies or class B felonies when committed by an individual. Felonies committed by a corporation or an unincorporated association are unclassified.

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(1) Class A felonies are crimes so designated by statute within or outside this code and any crime defined by statute outside of this code for which the maximum penalty, exclusive of fine, is imprisonment in excess of 7 years.

(2) Class B felonies are crimes so designated by statute within or outside this code and any crime defined outside of this code for which the maximum penalty, exclusive of fine, is imprisonment in excess of one year but not in excess of 7 years.

IV. Misdemeanors are either class A misdemeanors or class B misdemeanors when committed by an individual. Misdemeanors committed by a corporation or an unincorporated association are unclassified.

(a) A class A misdemeanor is:

(1) Any crime so designated by statute within or outside this code and any crime defined outside of this code for which the maximum penalty, exclusive of fine, is imprisonment not in excess of one year; or

(2) Any crime designated within or outside this code as a misdemeanor, without specification of the classification.

(b) A class B misdemeanor is any crime so designated by statute within or outside this code and any crime defined outside of this code for which the maximum penalty does not include any term of imprisonment or any fine in excess of the maximum

provided for a class B misdemeanor in RSA 651:2, IV(a).

V. A violation is an offense so designated by statute within or outside this code and, except as provided in this paragraph, any offense defined outside of this code for which there is no other penalty provided other than a fine or fine and forfeiture or other civil penalty. In the case of a corporation or an unincorporated association, offenses defined outside of this code are violations if the amount of any such fine provided does not exceed \$50.

V-a. The violation of any requirement created by statute or by municipal regulation enacted pursuant to an enabling statute, where the statute neither specifies the penalty or offense classification, shall be deemed a violation, and the penalties to be imposed by the court shall be those provided for a violation under RSA 651:2.

VI. Prior to or at the time of arraignment, the state may, in its discretion, charge any offense designated a misdemeanor, as defined by paragraph IV, as a violation. At such time, the prosecutor shall make an affirmative statement to the court as to whether he intends to proceed under this paragraph. In such cases the penalties to be imposed by the court shall be those provided for a violation under RSA 651:2. This paragraph shall not apply to any offense for which a statute prescribes an enhanced penalty for a subsequent conviction of the same offense.

VII. The state may change any offense designated or defined as a class A misdemeanor as defined by paragraph IV to a class B misdemeanor, so long as no element of the offense involves an act of violence or threat of violence. For purposes of this paragraph, the term "act of violence" means attempting to cause or purposely or recklessly causing bodily injury or serious bodily injury with or without a deadly weapon; and the term "threat of violence" means placing or attempting to place another in fear of imminent bodily injury either by physical menace or by threats to commit a crime against the person of the other. The state may change an offense pursuant to this paragraph if such change is in the interest of public safety and welfare and is not inconsistent with the societal goals of deterrence and prevention of recidivism, as follows:

(a) In its own discretion prior to or at the time of arraignment in the district court;

(b) In its own discretion following an entry of appeal in the superior court or within 20 days thereafter;

(c) With the agreement of the person charged at any other time; or

(d) In its own discretion, following entry of a complaint at a regional jury trial court or within 21 days thereafter.

VIII. If a person convicted of a class A misdemeanor has been sentenced and such sentence does

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not include any period of actual incarceration or a suspended or deferred jail sentence or any fine in excess of the maximum provided for a class B misdemeanor in RSA 651:2, IV(a), the court shall record such conviction and sentence as a class B misdemeanor.

Source. 1971, 518:1. 1973, 370:26-28. 1983, 382:7. 1988, 225:2. 1992, 269:1, 2. 1995, 277:21. 1996, 93:1. 2001, 274:5, eff. Jan. 1, 2002. 2006, 64:3, eff. Jan. 1, 2007.

Title LXII New Hampshire Criminal Code

Chapter 651 – Sentences

General Provisions

Section 651:2

651:2 Sentences and Limitations. –

I. A person convicted of a felony or a Class A misdemeanor may be sentenced to imprisonment, probation, conditional or unconditional discharge, or a fine.

II. If a sentence of imprisonment is imposed, the court shall fix the maximum thereof which is not to exceed:

- (a) Fifteen years for a class A felony,
- (b) Seven years for a class B felony,
- (c) One year for a class A misdemeanor,

(d) Life imprisonment for murder in the second degree, and, in the case of a felony only, a minimum which is not to exceed $\frac{1}{2}$ of the maximum, or if the maximum is life imprisonment, such minimum term as the court may order.

II-a. A person convicted of murder in the first degree shall be sentenced as provided in RSA 630:1-a.

II-b. A person convicted of a second or subsequent offense for the felonious use of a firearm, as provided in RSA 650-A:1, shall, in addition to any punishment provided for the underlying felony, be

given a minimum mandatory sentence of 3 years imprisonment. Neither the whole nor any part of the additional sentence of imprisonment hereby provided shall be served concurrently with any other term nor shall the whole or any part of such additional term of imprisonment be suspended. No action brought to enforce sentencing under this section shall be continued for sentencing, nor shall the provisions of RSA 651-A relative to parole apply to any sentence of imprisonment imposed.

II-c. [Repealed.]

II-d. A person convicted of manslaughter shall be sentenced as provided in RSA 630:2, II.

II-e. To the minimum sentence of every person who is sentenced to imprisonment for a maximum of more than one year shall be added a disciplinary period equal to 150 days for each year of the minimum term of the sentence, to be prorated for any part of the year. The presiding justice shall certify, at the time of sentencing, the minimum term of the sentence and the additional disciplinary period required under this paragraph. This additional disciplinary period may be reduced for good conduct as provided in RSA 651-A:22. There shall be no addition to the sentence under this section for the period of pre-trial confinement for which credit against the sentence is awarded pursuant to RSA 651-A:23.

II-f. A person convicted of violating RSA 159:3-a, I shall be sentenced as provided in RSA 159:3-a, II and III.

II-g. If a person is convicted of a felony, an element of which is the possession, use or attempted use of a deadly weapon, and the deadly weapon is a firearm, such person may be sentenced to a maximum term of 20 years' imprisonment in lieu of any other sentence prescribed for the crime. The person shall be given a minimum mandatory sentence of not less than 3 years' imprisonment for a first offense and a minimum mandatory sentence of not less than 6 years' imprisonment if such person has been previously convicted of any state or federal offense for which the maximum penalty provided was imprisonment in excess of one year, and an element of which was the possession, use or attempted use of a firearm. Neither the whole nor any part of the minimum sentence imposed under this paragraph shall be suspended or reduced.

III. A person convicted of a class B misdemeanor may be sentenced to conditional or unconditional discharge, a fine, or other sanctions, which shall not include incarceration or probation but may include monitoring by the department of corrections if deemed necessary and appropriate.

III-a. A person convicted of a violation may be sentenced to conditional or unconditional discharge, or a fine.

IV. A fine may be imposed in addition to any sentence of imprisonment, probation, or conditional discharge. The limitations on amounts of fines authorized in subparagraphs (a) and (b) shall not include the

amount of any civil penalty, the imposition of which is authorized by statute or by a properly adopted local ordinance, code, or regulation. The amount of any fine imposed on:

(a) Any individual may not exceed \$4,000 for a felony, \$2,000 for a class A misdemeanor, \$1,200 for a class B misdemeanor, and \$1,000 for a violation.

(b) A corporation or unincorporated association may not exceed \$100,000 for a felony, \$20,000 for a misdemeanor and \$1,000 for a violation. A writ of execution may be issued by the court against the corporation or unincorporated association to compel payment of the fine, together with costs and interest.

(c) If a defendant has gained property through the commission of any felony, then in lieu of the amounts authorized in paragraphs (a) and (b), the fine may be an amount not to exceed double the amount of that gain.

V. (a) A person may be placed on probation if the court finds that such person is in need of the supervision and guidance that the probation service can provide under such conditions as the court may impose. The period of probation shall be for a period to be fixed by the court not to exceed 5 years for a felony and 2 years for a class A misdemeanor. Upon petition of the probation officer or the probationer, the period may be terminated sooner by the court if the conduct of the probationer warrants it.

(b) In cases of persons convicted of felonies or class A misdemeanors, or in cases of persons found to be habitual offenders within the meaning of RSA 259:39 and convicted of an offense under RSA 262:23, the sentence may include, as a condition of probation, confinement to a person's place of residence for not more than one year in case of a class A misdemeanor or more than 5 years in case of a felony. Such home confinement may be monitored by a probation officer and may be supplemented, as determined by the department of corrections or by the county department of corrections, by electronic monitoring to verify compliance.

(c) Upon recommendation by the department of corrections or by the county department of corrections, the court may, as a condition of probation, order an incarceration-bound offender placed in an intensive supervision program as an alternative to incarceration, under requirements and restrictions established by the department of corrections or by the county department of corrections.

(d) Upon recommendation by the department of corrections or by the county department of corrections, the court may sentence an incarceration-bound offender to a special alternative incarceration program involving short term confinement followed by intensive community supervision.

(e) The department of corrections and the various county departments of corrections shall adopt rules governing eligibility for home confinement,

intensive supervision and special alternative incarceration programs.

(f) Any offender placed in a home confinement, intensive supervision or special alternative incarceration program who violates the conditions or restrictions of probation shall be subject to immediate arrest by a probation officer or any authorized law enforcement officer and brought before the court for an expeditious hearing pending further disposition.

(g) The court may include, as a condition of probation, restitution to the victim as provided in RSA 651:62-67 or performance of uncompensated public service as provided in RSA 651:68-70.

(h) In cases of a person convicted of a felony or class A misdemeanor, a court may sentence such person to 7 consecutive 24-hour periods to be served at the state-operated 7-day multiple DWI offender intervention detention center program established under RSA 265-A:40, if the evidence demonstrates that alcohol was a contributing factor in the commission of the offense and provided that space is available in the program and such person pays the fees for the program in full prior to admission.

VI. (a) A person may be sentenced to a period of conditional discharge if such person is not imprisoned and the court is of the opinion that probationary supervision is unnecessary, but that the defendant's conduct should be according to conditions determined by the court. Such conditions may include:

(1) Restrictions on the defendant's travel, association, place of abode, such as will protect the victim of the crime or insure the public peace;

(2) An order requiring the defendant to attend counselling or any other mode of treatment the court deems appropriate;

(3) Restitution to the victim; and

(4) Performance of uncompensated public service as provided in RSA 651:68-70.

(b) The period of a conditional discharge shall be 3 years for a felony and one year for a misdemeanor or violation. However, if the court has required as a condition that the defendant make restitution or reparation to the victim of the defendant's offense or that the defendant perform uncompensated public service and that condition has not been satisfied, the court may, at any time prior to the termination of the above periods, extend the period for a felony by no more than 2 years and for a misdemeanor or violation by no more than one year in order to allow the defendant to satisfy the condition. During any period of conditional discharge the court may, upon its own motion or on petition of the defendant, discharge the defendant unconditionally if the conduct of the defendant warrants it. The court is not required to revoke a conditional discharge if the defendant commits an additional offense or violates a condition.

VI-a. [Repealed.]

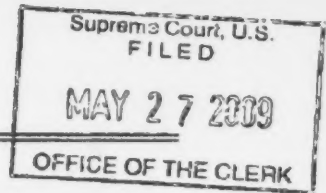
VI-b. A person sentenced to conditional discharge under paragraph VI may apply for annulment of the criminal record under RSA 651:5.

VII. When a probation or a conditional discharge is revoked, the defendant may be fined, as authorized by paragraph IV, if a fine was not imposed in addition to the probation or conditional discharge. Otherwise the defendant shall be sentenced to imprisonment as authorized by paragraph II.

VIII. A person may be granted an unconditional discharge if the court is of the opinion that no proper purpose would be served by imposing any condition or supervision upon the defendant's release. A sentence of unconditional discharge is for all purposes a final judgment of conviction.

Source. 1971, 518:1. 1973, 370:2. 1974, 34:13, 14. 1977, 397:1; 403:2. 1979, 126:6; 377:8. 1981, 397:1. 1982, 36:2. 1983, 382:8. 1986, 156:4. 1988, 19:4. 1989, 295:2. 1990, 95:1. 1991, 355:102. 1992, 19:1; 269:8-10; 284:85, 86, XIII. 1994, 192:1, 2. 1995, 237:4. 1996, 93:2-9. 1998, 366:3. 1999, 158:4. 2006, 163:1, eff. Jan 1, 2007; 260:33, eff. Jan. 1, 2007.

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No. 08-1202



**In The
Supreme Court of the United States**

IMS HEALTH, INC. and VERISPAN, LLC,

Petitioners,

v.

KELLY A. AYOTTE, As Attorney General
Of The State Of New Hampshire,

Respondent.

**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The First Circuit**

BRIEF IN OPPOSITION

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COUNTERSTATEMENT OF QUESTIONS PRESENTED

1. Whether the First Circuit correctly held that the Prescription Information Law regulates conduct, not First Amendment protected speech, of data miners.
2. Whether the First Circuit, in its alternative holding, correctly applied the *Central Hudson* test in holding that the Prescription Information Law passes constitutional muster.

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STATEMENT OF THE CASE

1. The New Hampshire legislature enacted the Prescription Information Law ("PIL")¹ in 2006 as a measure to control health care costs in New Hampshire, to protect the health and safety of New Hampshire's citizens, and to protect the privacy of doctors and patients who use prescription drugs. Before the PIL came into effect, data mining companies such as Petitioners IMS Health and Verispan were able to purchase information from pharmacies about what individual physicians prescribed to their patients. The data mining companies would aggregate the information and sell it to pharmaceutical companies for use in their marketing activities. Pharmaceutical companies used the information to target doctors for office visits by sales representatives (called "detailing"). Detailing is generally confined to high-margin, high profit drugs, for which the manufacturer has a substantial incentive to increase sales. Thus, the work of pharmaceutical sales representatives drives drug use toward the most expensive products, and contributes to the strain on health care budgets for individuals as well as health care programs, especially Medicaid.

Pharmaceutical manufacturers invest considerable resources in marketing efforts; for example, in 2000, the industry spent around \$15.7 billion on

¹ 2006 N.H. Laws 328, codified at N.H. Rev. Stat. § 318:47-f, N.H. Rev. Stat. § 318:47-g, and N.H. Rev. Stat. § 318-B:12.

marketing, \$4 billion of which was dedicated to direct-to-physician strategies. In fact, the large pharmaceutical companies spend a higher proportion of their revenues on promotion, marketing, and administration than the proportion spent on research and development. Detailing in particular has a significant effect on physician prescribing behavior, yet physicians are often unaware of the substantial impact manufacturer promotional activities have on their prescription practices. The purpose of all this contact and communication by detailers is not to provide an unbiased review of the evidence, but rather to enhance sales of a given company's product, whether or not it is the most appropriate or cost-effective choice.

Because of its powerful effect on physicians' prescribing practices, detailing by pharmaceutical sales representatives has significant economic and clinical consequences for the health care system. Physicians' use of targeted prescriptions increases substantially after visits with sales representatives. This has important effects on the cost of medications since detailing is generally confined to high-margin, high profit drugs, for which the manufacturer has a substantial incentive to increase sales. The effect of detailing in driving physicians' prescribing practices to the newest, most costly products can also have an important effect on patients' clinical outcomes. Because full understanding of a drug's side effect profile may not be complete when the drug is first approved for marketing, detailing encourages the prescription of

new products that might be riskier to patients than known agents on the market.

The New Hampshire legislature sought to curb this escalating problem by enacting the PIL which, among other things, prohibits the use, transfer, license, or sale of prescription information containing prescriber-identifiable data for certain commercial purposes. By preventing the use of prescriber specific prescription information in detailing physicians, the Act would cause a shift in the message being provided by pharmaceutical representatives. Conversations between detailers and physicians would be less tailored by the detailer and his or her primary interest in the market share of the drug being promoted, and would focus more on the science of the drug. The PIL's restrictions are very narrowly targeted. The PIL does not prevent Petitioners from continuing to gather and analyze prescriber-identifiable information, nor does it prevent them from publishing, transferring, and selling this information to whomever they choose so long as the recipient does not use the information for marketing.

2. Petitioners filed an action for declaratory and injunctive relief in the United States District Court for the District of New Hampshire. Petitioners asserted that the PIL violates the First Amendment, the Commerce Clause, and is void for vagueness. No pharmaceutical companies joined the action. After a bench trial, the district court issued an order on April 30, 2007, ruling that the PIL violates Petitioners' First Amendment right to engage in commercial

speech, and enjoined its enforcement. Pet. App. 152-199. The Court made no ruling regarding IMS Health and Verispan's Commerce Clause claim. *Id.*

The respondent appealed, and the First Circuit Court of Appeals reversed. Pet. App. 1-51. The First Circuit first addressed the issue of standing and held that Petitioners lack standing to assert the First Amendment rights of pharmaceutical detailers and physicians. Pet. App. 13-14. The court explained that "[a] party ordinarily has no standing to assert the First Amendment rights of third parties." Pet. App. 13 (quoting *Wine & Spirits Retailers, Inc. v. Rhode Island*, 418 F.3d 36, 49 (1st Cir. 2005)). The First Circuit rejected Petitioners' argument that the exception laid down in *Craig v. Boren*, 429 U.S. 190, 194-95 (1976), applied because there was "no indication in the record that pharmaceutical companies, detailers, or physicians are somehow incapable of or inhibited from vindicating their own rights." Pet. App. 15. Recognizing this Court's willingness to relax third-party standing in the First Amendment context, the First Circuit noted that "this relaxation evinces nothing more than a receptiveness to facial attacks on allegedly overbroad laws," and that otherwise, hindrance remains a necessary prerequisite. *Id.* The court stated that it would therefore restrict its analysis to "whether the data miners' activities – the acquisition, aggregation, and sale of prescriber-identifiable data – constitute speech or conduct and whether New Hampshire's legitimate governmental interests are

sufficient to counterbalance any speech rights inherent therein." Pet. App. 16.

The First Circuit then turned to "the relatively narrow question" of whether the PIL's restrictions on transfers of prescriber-identifiable information from pharmacies to data miners and data miners to pharmaceutical companies regulate the conduct or speech of data miners. Pet. App. 19, 22. The court recognized that while "pure informational data can qualify for First Amendment protection," Pet. App. 19, there are "species of speech-related regulations that effectively lie beyond the reach of the First Amendment," Pet. App. 20. "[W]hy or how these content-based prohibitions manage to escape First Amendment scrutiny" the court described as a "doctrinal mystery." Pet. App. 21. The First Circuit provided its own explanation as follows:

In our view, the most natural explanation for this phenomenon is that this complex of de facto exceptions derives from a felt sense that the underlying laws are inoffensive to the core values of the First Amendment – inoffensive because they principally regulate conduct and, to the extent that they regulate speech at all, that putative speech comprises items of nugatory informational value. It is this unusual combination of features that distinguishes these laws and places them outside the ambit of the First Amendment.

Pet. App. 21-22. The court concluded that the restriction the PIL places on the data miners' activities falls

outside the First Amendment as “a restriction on the conduct, not the speech, of the data miners,” describing the data miners’ activities as “a situation in which information itself has become a commodity.” Pet. App. 22-23. The First Circuit rejected Petitioners’ assertion that the PIL limits the free flow of information, noting that the PIL “simply does not prevent any information-generating activities” because Petitioners “may still gather and analyze this information; and may publish, transfer, and sell this information to whomever they choose *so long as that person does not use the information for detailing.*” Pet. App. 23-24 (emphasis in original). The court recognized that Petitioners’ true complaint was not the free flow of information, but rather their ability to turn a profit, a concern that the First Amendment does not safeguard against. Pet. App. 24.

Limiting its analysis to the restrictions the PIL places on data miners’ activities,² the First Circuit held that “the challenged portions of the Prescription Information Law fall outside the compass of the First Amendment. They thus engender rational basis review as a species of economic regulation.” Pet. App. 26. Because Petitioners conceded that the PIL survived rational basis review, the First Circuit held that their challenge under the Free Speech Clause failed. *Id.*

² The court left open the question of whether the PIL restricts First Amendment protected speech of detailers or doctors. Pet. App. 24.

3. The First Circuit went on to provide an alternative ground for its decision. Pet. App. 26-42. Again restricting its analysis to the activities of data miners, the court reasoned that even if "the acquisition, manipulation, and sale of prescriber-identifiable data comes within the compass of the First Amendment," such transactions are commercial speech, if speech at all. Pet. App. 27. The First Circuit rejected Petitioners' narrow definition of commercial speech limited to activities "propos[ing] a commercial transaction," see *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473-74 (1989), in favor of the broader definition adopted by this Court in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 561 (1980) (defining commercial speech as "expression related solely to the economic interest of the speaker and its audience"). Pet. App. 27-28.

The First Circuit then proceeded to apply the *Central Hudson* test. Examining whether the government had advanced a substantial state interest in support of the PIL, the court observed that the State had identified three interests served by the PIL: "[1] maintaining patient and prescriber privacy, [2] protecting citizens' health from the adverse effects of skewed prescribing practices, and [3] cost containment." Pet. App. 28. For simplicity's sake, the court restricted its analysis to the third of these interests. *Id.* Noting that "[f]iscal problems have caused entire civilizations to crumble," the First Circuit concluded that "cost containment is most assuredly a substantial governmental interest." Pet. App. 28.

Next, the First Circuit examined the second step of the *Central Hudson* test: whether the regulation directly advances the State's interest. The court explained that while the State "must demonstrate that the harms it recites are real" and that the restrictions at issue "will in fact alleviate them to a material degree," certitude is not required. Pet. App. 29. The court observed that "the state's evidence falls into three evidentiary subsets"; (1) "evidence showing that detailing increases the cost of prescription drugs"; (2) evidence "showing that prescribers' histories enhance the success of detailing"; and (3) "evidence indicating that, notwithstanding these escalating costs, detailing does not contribute to improved patients' health." Pet. App. 29-30. Thus, the State reasoned that "stripping detailers of the ability to use prescribers' histories as a marketing tool" will decrease the amount of more expensive brand-name drugs dispensed, thus reducing or containing overall costs. Pet. App. 30.

As to the first subset of evidence, the First Circuit found it "unarguable" that detailing increases the cost of prescription drugs, noting "[t]he fact that the pharmaceutical industry spends over \$4,000,000,000 annually on detailing bears loud witness to its efficacy." Pet. App. 30-31. The court also found that "[t]estimony adduced at trial reinforced these common-sense conclusions." Pet. App. 31. Turning to the second and third step in the analysis, the First Circuit summarized the evidence presented by each side at trial and found that

[t]he state provided competent evidence that detailing increases the prescription of brand-name drugs, that brand-name drugs tend to be more expensive, that detailers' possession of prescribing histories heightens this exorbitant effect, that many aggressively detailed drugs provide no benefit vis-à-vis their far cheaper generic counterparts, and that detailing had contributed to pharmaceutical scandals endangering both the public health and the public coffers.

Pet. App. 34-35. While admitting that the State's evidence was "not overwhelming," Pet. App. 33, the First Circuit found that the district court "subjected the state to a level of scrutiny far more exacting than is required for commercial speech," Pet. App. 34. The First Circuit also criticized the district court for "disregard[ing] the constraints under which states operate in formulating public policy on cutting-edge issues," noting that "New Hampshire was the first state to deny detailers access to prescribing histories." Pet. App. 35-36. Thus, the evidence the district court demanded of the State "simply does not exist." Pet. App. 36. The First Circuit found it appropriate to "allow the state legislature some leeway to experiment with different methods of combating a social and economic problem of growing magnitude." Pet. App. 36-37. The court rejected Petitioners' attack on the sufficiency of the legislative record, finding it "fanciful to suggest that the congressional record in *Turner* [*Broadcast Systems v. FCC*, 520 U.S. 180, 199 (1997)] represents the threshold for deference." Pet.

App. 37. "Given the contents of the legislative record," the First Circuit found that "deference is in order." *Id.*

Thus, on the second step of the *Central Hudson* test, the First Circuit "conclude[d] that the state adequately demonstrated that the Prescription Information Law is reasonably calculated to advance its substantial interest in reducing overall health care costs within New Hampshire." Pet. App. 38.

Finally, the First Circuit turned to the third *Central Hudson* question: "whether the regulation is no more extensive than necessary to serve the state's interest in cost containment." *Id.* Applying the rule set forth in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002) – that regulating speech must be a last resort – the First Circuit considered, and rejected, the three alternative measures suggested by the district court. Pet. App. 38-41. The court reasoned that (1) a ban on gifts to physicians would target a harm the legislature did not deem central to its aims, and would have the unintended consequence of cutting off the flow of free samples which are often dispensed by physicians to indigent patients; (2) a program of "counter-detailing" by the State was not a feasible solution given that pharmaceutical companies spend over \$4,000,000,000 per year on detailing; and (3) retooling the State's Medicaid program in the manner suggested by the district court was impracticable, incomplete, and would be an attempt to remedy compromised prescribing habits of physicians after the fact. Pet. App. 39-40. The First Circuit concluded that neither Petitioners nor the

district court had identified an appropriate alternative, and held that the PIL "is no more restrictive than necessary to accomplish [its] goals." Pet. App. 41.

Having held that the challenged portions of the PIL survive intermediate scrutiny, Pet. App. 41, the First Circuit turned to Petitioners' contention that the PIL is void for vagueness, Pet. App. 42-46, and Petitioners' Commerce Clause challenge, Pet. App. 46-50. The First Circuit rejected both claims, holding that the PIL "is sufficiently clear to withstand [Petitioners'] vagueness challenge," Pet. App. 43, and that the PIL is susceptible to a construction that does not violate the Commerce Clause, Pet. App. 48-50.

In conclusion, the First Circuit reversed the decision of the district court and vacated the injunction against enforcement of the PIL. Pet. App. 50-51.

4. Judge Lipez issued a separate opinion concurring in part and dissenting in part. Pet. App. 51-151. While he agreed with the majority's conclusion that Petitioners' activity "is not speech within the purview of the First Amendment," he disagreed with the majority's refusal to address what he described as "the First Amendment issue at the core of this case," namely, "whether the Act restricts protected commercial speech *between detailers and prescribers* and, if so, whether the State can justify that restriction under" the *Central Hudson* test. Pet. App. 51-52 (emphasis added). After examining the issue of standing, Pet. App. 52-63, Judge Lipez went on to address the

First Amendment issue avoided by the majority, Pet. App. 86-97. He concluded that because the PIL indirectly targets the speech of detailers in their sales messages to prescribers, the regulation "is a limitation on commercial speech, and the State consequently must bear the burden of demonstrating that it satisfies the *Central Hudson* test." Pet. App. 96. Applying that test, he concluded that the PIL survives intermediate scrutiny. Pet. App. 151. He agreed with the majority that the PIL is sufficiently clear to withstand Petitioners' vagueness challenge. *Id.* With regard to Petitioners' Commerce Clause claim, he would have remanded the case to the district court for it to address the issue in the first instance. Pet. App. 142.

5. The First Circuit denied Petitioners' request for rehearing and rehearing en banc, Pet. App. 201, as well as Petitioners' request to stay mandate pending filing for writ of certiorari. Petitioners then filed an emergency application to the Honorable David Souter to stay mandate pending certiorari, which was denied.

REASONS FOR DENYING THE PETITION

Contrary to Petitioners' assertions, the First Circuit decision in this case does not threaten the "basic economic viability of the Internet" or publications such as the daily stock report of the *Wall Street Journal*. In ruling that Petitioners' conduct falls outside

the protections of the First Amendment, the First Circuit considered the specific nature of the information exchanges regulated by the PIL. The court found that transfers of prescriber-identifiable information "undertaken to increase one party's bargaining power in negotiations" were not the sort of exchanges valued by the Supreme Court's First Amendment jurisprudence. Pet. App. 26. This may not hold true for other forms of informational exchanges occurring through the Internet or traditional media.³ The First Circuit expressly declined to issue a more expansive ruling, explaining: "Were the state capable of forbidding every use of information regardless of the specific nature of either the use or the information, the state's power to control the flow of information would be nearly absolute." Pet. App. 18.

Petitioners have failed to identify any grounds warranting a grant of certiorari in this case. They first assert that the First Circuit's ruling that their data mining activities fall outside the protection of the First Amendment warrants review because it is in irreconcilable conflict with this Court's First Amendment precedent and because of the impact such a rule will have on the free flow of information. The decision

³ With regard to the *Wall Street Journal* and other such publications, there is a vast difference between silencing the media whose sole purpose is communicating information to the public, and prohibiting the dissemination of information from one private company to another private company for economic gain. Pet. App. 23-24.

below, however, fully comports with relevant First Amendment precedent and is limited to the PIL's regulation of data mining activities, making it unlikely that it will have the wide-reaching effects on the free flow of information suggested by Petitioners.

Next, Petitioners assert that the case implicates a conflict in the circuits concerning the proper definition of "commercial speech," and would also provide this Court with the opportunity to revisit whether commercial speech should remain subject to lessened First Amendment protection. This case would provide a poor vehicle for any further refinement of the *Central Hudson* framework given the First Circuit's ruling on standing. This Court has been reluctant to adopt an all-purpose test to distinguish commercial from noncommercial speech under the First Amendment, and the First Circuit's narrow holding in this case does not implicate the concerns raised by some Members of this Court regarding the *Central Hudson* analysis. Moreover, the First Circuit's *Central Hudson* analysis appears in the court's alternative ground for reversal; thus, if this Court agrees that Petitioners' data mining activities fall outside the protection of the First Amendment, then there would be no need to reach the issues relating to the definition of commercial speech and the appropriate level of judicial scrutiny for legislation restricting such speech. In any event, Petitioners' challenge to the First Circuit's *Central Hudson* analysis amounts to nothing more than a request for error correction, and thus does not merit a grant of certiorari.

Finally, Petitioners assert that the daily impact of the PIL on their activities and the adoption of similar statutes in other states necessitate this Court's prompt review of the statute's constitutionality. Reviewing the statute in the context of this case, however, would not resolve all potential First Amendment challenges that could arise from this or other similar statutes. Because the First Circuit limited its analysis to the PIL's effects on data mining activities only, the statute's effect on communications between detailers and doctors remains subject to future challenge. Because no pharmaceutical company is a party to this case, the record below is insufficient to address the First Amendment issues detailers could raise in a future challenge. Considering the First Circuit's limited holding and the lack of a complete record, this case is a poor vehicle through which to address the First Amendment issues raised by the PIL. A review by this Court of the constitutionality of the PIL is better left for another case.

Accordingly, the petition for a writ of certiorari should be denied.

I. THE FIRST CIRCUIT'S HOLDING THAT THE PRESCRIPTION INFORMATION LAW DOES NOT IMPLICATE THE FIRST AMENDMENT RIGHTS OF DATA MINERS DOES NOT CONFLICT WITH THE DECISIONS OF THIS COURT

The First Circuit's holding that the PIL regulates conduct, not speech, was not necessary to its decision

and not in conflict with this Court's precedents. The decision does not conflict with precedent of this Court establishing that purely factual matters of public interest may claim First Amendment protection. The First Circuit expressly recognized that "pure informational data can qualify for First Amendment protection." Pet. App. 19 (citing *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446-47 (2nd Cir. 2001), and *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976)). The decision below fully comports with relevant First Amendment precedents; Petitioners simply disagree with how the First Circuit applied those precedents to the facts of this case. Thus, Petitioners' challenge to the First Circuit's decision that data mining activities fall outside the protection of the First Amendment is nothing more than a request for error correction by this Court. In any event, Petitioners greatly overstate the import of the court's first holding. The First Circuit went on to fully consider the commercial speech arguments and held that the law satisfies *Central Hudson*. Indeed, the concurring judge agreed with the majority regarding the application of *Central Hudson*.

1. The First Circuit's holding does not hinge on the *factual* nature of the data being regulated; rather, the court found that the statute regulates conduct, not speech, because it does not prevent any information-generating activities. The PIL does not prevent Petitioners from gathering and analyzing prescriber-identifiable information, nor does it prevent them

from publishing, transferring, and selling this information to whomever they choose so long as the recipient does not use the information for marketing. Thus, the PIL does not prevent Petitioners from *communicating* information; rather, the PIL's restrictions affect the *value* of that information as a commodity in the marketplace due to the restrictions it places on the *recipient's* use of the information. The PIL's restrictions on a third party's use of information do not abridge these Petitioners' freedom of speech under the First Amendment.⁴

The PIL is distinguishable from advertising regulations. Unlike advertising regulations, which restrict the dissemination of information *about* commercial transactions, the PIL regulates commercial transactions themselves. It is the communicative nature of advertising that brings such speech within the ambit of First Amendment protection. *See Central Hudson*, 447 U.S. at 563 ("The First Amendment's concern for commercial speech is based on the informational function of advertising."). While an advertisement constitutes "speech" within the scope of the First Amendment because it expresses a message by "propos[ing] a commercial transaction," *see Virginia*

⁴ As mentioned earlier, the First Circuit held that the Petitioners lacked standing to assert the First Amendment rights of pharmaceutical detailers and physicians, and thus restricted its analysis to whether data miners' activities constitute speech or conduct. The First Circuit left open the question of whether the PIL restricts First Amendment protected speech of detailers or doctors. Pet. App. 24.

Pharmacy, 425 U.S. at 762, the actual transaction which follows is not the expression of a message, commercial or otherwise, and therefore does not fall within the First Amendment's protection, *see Ohralik v. Ohio State Bar Assoc.*, 436 U.S. 447, 455 (1978) (recognizing that "expression[s] concerning purely commercial transactions ha[ve] come within the ambit of the [First] Amendment's protection") (emphasis added). Regulating commercial transactions themselves does not implicate the First Amendment. *See 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 499 (1996) (recognizing the State's power to regulate commercial transactions as a justification to regulate commercial speech linked to those transactions: "The entire commercial speech doctrine, after all, represents an accommodation between the right to speak and hear expressions *about* goods and services and the right of government to regulate the sales *of* such goods and services.") (Emphasis in original) (citation omitted). The fact that the commodity being regulated in this case is a collection of information does not bring the data miners' activities within the protections of the First Amendment. *See Rumsfeld v. Forum for Academic and Institutional Rights, Inc.*, 547 U.S. 47, 126 S. Ct. 1297, 1308 (2006), quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949) ("[I]t has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed."); *see also Reno v. Condon*, 528 U.S. 141, 148 (2000)

(holding that data is a "thing in interstate commerce").

The First Circuit's decision does not conflict with this Court's decisions in *Thompson*, 535 U.S. 357, *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749 (1985), and *LAPD v. United Reporting Publishing Corp.*, 528 U.S. 32 (1999), none of which addressed the speech/conduct question. In *Thompson*, an advertising case, this Court did not consider whether the statute at issue restricted speech protected by the First Amendment because the parties agreed that the statute prohibited commercial speech. 535 U.S. at 366. Similarly, in *Dun & Bradstreet*, a defamation action, the issue of what constitutes speech under the First Amendment did not arise. 472 U.S. 749. The issue was not whether the defamatory statements at issue constituted speech protected by the First Amendment, but rather whether the statements involved matters of public concern which would restrict the damages the plaintiff could obtain. *Id.* at 757-63. Finally, in *United Reporting* the Ninth Circuit did not consider whether a private publishing service's provision of arrest records to its customers constituted speech versus conduct, but rather whether its use of the information constituted commercial speech versus fully-protected First Amendment speech. 146 F.3d 1133, 1136 (9th Cir. 1999). On appeal to the Supreme Court, the police department "concede[d] that if [the publishing service] independently acquires the data, the First Amendment protects its right to communicate it to others." *United Reporting*,

528 U.S. at 46. Thus, the speech/conduct question at issue in the instant case was not considered in *United Reporting*.

2. The First Circuit's ruling that the PIL regulates Petitioners' conduct, not protected speech, also does not conflict with the rulings of other circuits. Although the Second Circuit held in *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, that "computer code, and computer programs constructed from code *can* merit First Amendment protection," *id.* at 449 (emphasis added), the Court recognized that computer programs do not *always* communicate speech protected by the First Amendment, *id.* at 448-49 (discussing *Commodity Futures Trading Commission v. Vartuli*, 228 F.3d 94, 109-12 (2nd Cir. 2000)). In *Vartuli*, the Second Circuit considered the *manner* in which a computer program was used, and denied First Amendment protection to the program in that case even though it was expressed in words. *Vartuli*, 228 F.3d at 111.

Petitioners also suggest that the First Circuit's decision conflicts with rulings of the D.C. Circuit. However, none of the cases Petitioners cite, *Nat'l Cable Television Ass'n, Inc. v. FCC*, 555 F.3d 996 (D.C. Cir. 2009), *Trans Union LLC v. FTC*, 295 F.3d 42 (D.C. Cir. 2002), and *Trans Union Corp. v. FTC*, 245 F.3d 809, *reh'g denied*, 267 F.3d 1138 (D.C. Cir. 2001), *cert. denied*, 536 U.S. 915 (2002), address the speech/conduct question. In *Nat'l Cable*, all parties proceeded on the basis that there was a regulation of commercial speech. 555 F.3d at 1000. Similarly, in *Trans*

Union, the D.C. Circuit applied First Amendment scrutiny without considering the threshold question of whether the sale of target marketing lists constitutes protected speech. 245 F.3d at 818. Because the speech/conduct question was not raised or addressed in those cases, they do not directly conflict with the First Circuit's ruling that the PIL regulates data miners' conduct, not First Amendment protected speech.

Although the Tenth Circuit *did* directly address the threshold question for application of the First Amendment in both *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232-33 (10th Cir. 1999) and *Lanphere & Urbaniak v. Colorado*, 21 F.3d 1508, 1512-13 (10th Cir. 1994), *cert. denied*, 513 U.S. 1044, those cases are distinguishable. The companies challenging the regulations at issue in *U.S. West* and *Lanphere* directly sought to use the information for their own marketing; therefore, the effect of the regulations on their First Amendment speech rights are more analogous to the rights of pharmaceutical detailers, not data miners. The First Circuit here did not consider whether the PIL restricts First Amendment protected speech of pharmaceutical detailers, leaving that question unanswered.

The First Circuit correctly concluded that the restriction the PIL places on the data miners' activities falls outside the First Amendment as a restriction on the conduct, not the speech, of the data miners. The court's holding does not conflict with decisions of this Court or the rulings of other circuits,

and does not warrant review by this Court. Moreover, the holding is not necessary to the decision since the court went on to fully consider the commercial speech argument.

II. THE FIRST CIRCUIT CORRECTLY RULED IN ITS ALTERNATIVE HOLDING THAT THE PIL PASSES CONSTITUTIONAL MUSTER

As an alternative ground for its holding, the First Circuit ruled that even if the data miners' activities come within the compass of the First Amendment, such transactions constitute commercial speech, if speech at all, and the PIL survives intermediate scrutiny. Petitioners claim this holding warrants review on two grounds. First, Petitioners assert it provides an opportunity for this Court to clarify the definition of "commercial speech," and to revisit whether commercial speech should remain subject to lessened First Amendment protection. Second, Petitioners erroneously contend that the First Circuit's holding that the PIL survives First Amendment scrutiny was wrong.

A. This Case Does Not Provide Occasion For This Court to Revisit the Commercial Speech Doctrine

This Court has not adopted an all-purpose test to distinguish commercial from noncommercial speech under the First Amendment. Although the Court first defined the category of commercial speech as "speech

which does no more than propose a commercial transaction," *Virginia Pharmacy*, 425 U.S. at 762, in later opinions the Court has "also suggested that such lesser protection was appropriate for a somewhat larger category of commercial speech – 'that is, expression related solely to the economic interests of the speaker and its audience.'" *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 422 (1993) (quoting *Central Hudson*, 447 U.S. at 561). The Court has recognized "the difficulty of drawing bright lines that will clearly cabin commercial speech in a distinct category," *Discovery Network*, 507 U.S. at 419, noting that "ambiguities may exist at the margins of the category of commercial speech," *Edenfield v. Fane*, 507 U.S. 761, 765 (1993). This Court has been reluctant, for good reason, to reduce the doctrine to any simple rule or determinate criteria,⁵ and it should decline to do so now.

⁵ [The] Court has in its commercial speech doctrine persistently gestured toward the "common sense" distinction between commercial speech and speech at the First Amendment's core. The evaluations of "commonsense" are complex, contextual, and ultimately inarticulate; the Court's appeal to common sense acknowledges that the achievement of constitutional purposes cannot be reduced to any simple rule or determinate criteria. The judgments of common sense ultimately revolve around questions of social meaning; they turn on whether the utterance of a particular speaker should be understood as an effort to engage public opinion or instead simply sell products.

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Nor does this case provide occasion for this Court to revisit the applicability of *Central Hudson*'s intermediate scrutiny standard. For almost 30 years, this Court has consistently applied the intermediate scrutiny called for in *Central Hudson* in assessing First Amendment challenges to regulations of commercial speech. Although several Members of the Court have expressed concerns about the applicability of this standard and whether it should apply in particular cases, see *Thompson*, 535 U.S. at 367-68 (citing opinions in which Justices expressed doubts about the *Central Hudson* analysis), there is no need for the Court to break new ground in this case. In arguing that the PIL should be subjected to greater scrutiny than is called for by *Central Hudson*, Petitioners focus on the alleged social benefit of detailing. The First Circuit, however, did not consider the PIL's effect on speech between detailers and physicians, finding that Petitioners lack standing to assert the First Amendment rights of pharmaceutical detailers and physicians. The First Circuit's decision in this case, therefore, does not implicate the concerns raised by Petitioners, and thus it does not provide a useful vehicle for resolving any such doubts about *Central Hudson*. *Central Hudson* provides an adequate basis for decision in this case.

Robert Post, *The Constitutional Status of Commercial Speech* 48 UCLA L. Rev. 1, 18 (2000) (quotations, citations, and footnotes omitted).

B. The First Circuit's Application of *Central Hudson* Does Not Conflict With the Decisions of This Court or the Other Courts of Appeals

Petitioners erroneously contend that the First Circuit's decision "strays so far from accepted First Amendment principles as to merit this Court's review." To the contrary, the First Circuit's application of *Central Hudson* was straightforward and fully consistent with this Court's commercial speech precedents.

Central Hudson provides the following test for determining the constitutionality of a commercial speech restriction: If commercial speech is neither misleading nor related to unlawful activity, State regulation of that communication survives First Amendment scrutiny if (1) the State asserts a substantial interest to be achieved by the regulation; (2) the restriction directly advances the State interest involved; and (3) the governmental interest cannot be served by a more limited restriction on commercial speech. *Central Hudson*, 447 U.S. at 564.

Petitioners claim that the First Circuit's application of this test departed from relevant precedent in three ways. First, with regard to the "substantial interest" prong of the *Central Hudson* analysis, Petitioners assert that the First Circuit's ruling gives precedential sanction to a paternalistic agenda. Second, Petitioners contend that the First Circuit reached its decision on the second prong of the

analysis by giving improper deference to the State legislature and by failing to defer to the findings of the district court. Finally, Petitioners assert that the First Circuit erred in ruling that the PIL is no more restrictive than necessary, arguing it is both under- and over-inclusive. The First Circuit's decision, however, is consistent with the decisions of this Court. Regardless, this argument amounts to nothing more than a request for error correction, and thus does not merit a grant of certiorari.

1. The First Circuit's ruling that cost containment is a substantial governmental interest is constitutionally sound

1. Petitioners take portions of the decision below out of context in arguing that the First Circuit gives precedential sanction to a paternalistic agenda. Contrary to Petitioners' suggestions, the First Circuit did not conclude that the PIL satisfies the "substantial interest" requirement of *Central Hudson* based on the State's attempt to "improve the quality of interactions between detailers and physicians" by "level[ing] the playing field." These quoted passages appear in other portions of the First Circuit's opinion, not the court's application of *Central Hudson*. While recognizing that New Hampshire cited three separate governmental interests to be achieved by the PIL, the First Circuit expressly limited its analysis of the first prong of *Central Hudson* to the State's interest in cost containment. Pet. App. 28-29. The "paternalistic

goals" Petitioners criticize relate to the State's asserted interest in "protecting citizens' health from the adverse effects of skewed prescribing practices," an interest which the First Circuit did not address. See Pet. App. 28.

The State has an interest in health care costs directly in its role as Medicaid payor, and in controlling the cost of health care to its citizens. The First Circuit's ruling that cost containment suffices to satisfy the first prong of the *Central Hudson* test does not warrant review by this Court.

2. Petitioners erroneously assert that the First Circuit held they lacked standing to challenge this asserted governmental interest because Petitioners themselves do not engage in detailing. Again, Petitioners take portions of the First Circuit opinion out of context. The First Circuit held that Petitioners "must assert their own rights and explain how those rights are infringed by the operation of the Prescription Information Law." Pet. App. 16. The court went on to note that "this restriction on *jus tertii* rights does not prevent consideration of New Hampshire's interest in combating detailing." Pet. App. 16-17. Petitioners contort this straightforward ruling, mistakenly interpreting it as precluding Petitioners from disputing the State's interest in containing costs by limiting detailing. Nothing in the First Circuit's opinion supports this interpretation. To the contrary, the opinion describes Petitioners' evidence regarding the alleged positive effects of detailing, Pet. App. 30, 32-33, demonstrating that the court did in fact

consider Petitioners' argument that the PIL does not advance a cognizable state interest. The First Circuit's ruling on standing did not preclude Petitioners from disputing the State's assertion that it has a substantial interest in containing costs by limiting detailing, and does not warrant review by this Court.

2. The First Circuit's conclusion that the PIL directly advances the State's interest in cost containment does not warrant review by this Court

1. The First Circuit's application of the second prong of the *Central Hudson* test was fully consistent with this Court's commercial speech precedents. Contrary to Petitioners' contentions, the First Circuit did not hold that "New Hampshire need not justify the PIL through an adequate evidentiary record." Pet. 30. The court required the State to "demonstrate that the harms it recites are real and that [the] restriction will in fact alleviate them to a material degree." Pet. App. 29 (quoting *Edenfield*, 507 U.S. at 770-71). The court did not simply defer to legislative judgment, but rather carefully reviewed the evidence presented below and determined for itself that the evidence sufficiently demonstrated that the PIL satisfied the second prong of the *Central Hudson* test.⁶ Pet. App. 29-38.

⁶ The court correctly rejected Petitioners' challenge to the lack of empirical research. See *Turner Broadcast Sys. v. FCC*,
(Continued on following page)

This prong of *Central Hudson* requires a fact-intensive analysis that was given careful attention by both the majority and the concurring judge, and they both reached the same conclusion: the PIL is a narrow, targeted restriction that accomplishes the State's interest. Judge Lipez noted "evidence from multiple sources indicated that the expense of unnecessary brand-name prescribing has in the past ranged into the billions of dollars nationally." Pet. App. 123. He aptly concluded that

[t]his substantial evidence of needless spending, combined with evidence that detailing with prescriber-identifiable data contributes to that outcome, is enough to show that the [PIL] 'targets a concrete, non-speculative harm,' and that the Attorney General has sufficiently demonstrated that the State's interest in cost-containment would be furthered 'to a material degree' by the limitation on speech it seeks to achieve through the Prescription Act.

512 U.S. 622, 665 (1994) ("Sound policymaking often requires legislatures to forecast future events and to anticipate the likely impact of these events based on deductions and inferences for which complete empirical support may be unavailable."); *New State Ice Co. v. Liebman*, 285 U.S. 262, 311 (1932) ("a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments") (Brandeis, J., dissenting). Judge Lipez in his concurring opinion likewise found it "unreasonable in these circumstances to expect the Attorney General to provide extensive quantifiable data that might only become available after the statute has been in place for some time." Pet. App. 121.

Id. (citations omitted). Moreover, "the prohibited uses are narrowly defined," *Id.* at 77, such that "no message or interest of consequence . . . is foreclosed by the regulation."

Petitioners' disagreement on the sufficiency of the evidence does not warrant review by this Court.

2. Nor is this case a good vehicle for this Court to resolve the conflict in the circuits surrounding the application of *Bose Corp. v. Consumers Union of United States, Inc.*, 466 U.S. 485, 514 (1984), because the ultimate outcome of *this* case would not be any different had the First Circuit held *Bose's de novo* review standard inapplicable. It was the application of law to the facts that guided the court's conclusion in this case, not a contradictory view of the facts than the district court's. As the First Circuit pointed out, "[t]he raw facts are largely undisputed." Pet. App. 4; *see also* Pet. App. 63 (Lipez, concurring and dissenting) (drawing heavily on the recitation of facts set out by the district court and noting "[t]hose facts are largely undisputed; the parties primarily contest their legal significance"); *compare* Pet. App. 153-75 (district court's facts section) *to* Pet. App. 4-8 (First Circuit's background section). The First Circuit's reliance on the district court's factual findings is apparent from its cite to the district court's fact section as support for its description of detailing. *See* Pet. App. 4 n.1. Because the First Circuit found the fact to be largely undisputed, this case provides a poor vehicle for this Court to address the circuit conflict surrounding *Bose*.

3. The First Circuit's conclusion that the PIL satisfies the "reasonable fit" requirement does not warrant review by this Court

Petitioners erroneously contend that the PIL is simultaneously under- and over-inclusive in the speech it restricts, and thus cannot achieve the State's goals. This prong of the *Central Hudson* test does not require the government to adopt the least restrictive means necessary to serve the State's interests, but instead requires only a "reasonable fit" between the government's purpose and the means chosen to achieve it. *Fox*, 492 U.S. at 480. The PIL satisfies this requirement.

1. Petitioners' claim that the PIL is under-inclusive stems from an argument the State made in responding to Petitioners' Commerce Clause claim. The district court did not rule on that claim. On appeal to the First Circuit, the State argued that the Commerce Clause claim was not properly before the court because the district court had not ruled on the issue, and Petitioners had not filed a cross-appeal. Nevertheless, the First Circuit ruled on the issue, holding that the PIL does not violate the Commerce Clause because it can be interpreted "to affect only domestic transactions." Pet. App. 49. This interpretation of the PIL, however, "may not accomplish very much," Pet. App. 50, and leaves the PIL with "negligible impact," Pet. App. 143 (Lipez, C.J., concurring and dissenting), because pharmacies transmit the

data to data centers *outside* of New Hampshire before selling the data to Petitioners.

The PIL need not be given such a narrow construction in order to survive Petitioners' Commerce Clause challenge. Interpreting the PIL as affecting transactions outside of New Hampshire would not violate the Commerce Clause so long as the statute is construed as applying only to records originating in New Hampshire, and as regulating only entities doing business in New Hampshire. See *IMS Health Inc. et al. v. Sorrell*, 2009 WL 1098474, *17-19 (D. Vt. April 23, 2009). New Hampshire pharmacies should not be permitted to avoid compliance with the PIL simply by routing data through data centers outside of New Hampshire before selling the data to Petitioners. The PIL should be interpreted as affecting transactions outside New Hampshire when they involve prescriptions originating in New Hampshire.⁷ Interpreting the PIL in such a way allows the statute to accomplish what the State legislature intended,

⁷ Judge Lipez aptly noted that he was "not sure that the Attorney General understood the import of her statement that the Act regulates only in-state transactions." Pet. App. 148. Given that the proceedings below focused almost exclusively on the First Amendment issues, see Pet. App. 149 (Lipez, C.J.) (noting the parties only briefly addressed the Commerce Clause claim in their briefs to the First Circuit: "the plaintiffs' argument on the Commerce Clause spans only two and one-half pages in their sixty-page brief. The Attorney General's response is equally terse."), the State should not be held to an interpretation that would "leave the Act with negligible impact."

and addresses Petitioners' concerns that the statute is under-inclusive.

Nor is the PIL over-inclusive. Petitioners' argument that the PIL "equally applies when the detailing identifies a less expensive alternative" fails to take into account the realities of pharmaceutical detailing. The district court found that "[d]etailing is generally used only to market prescription drugs that are entitled to patent protection," Pet. App. 163, and the First Circuit noted that detailing "is time-consuming and expensive work, not suited to the marketing of lower-priced bioequivalent generic drugs," Pet. App. 6. Petitioners' argument that the PIL is over-inclusive because it inhibits competition between patent-protected brands is also unpersuasive since the PIL affects all brands equally, and therefore does not advantage any one brand over another.

2. Petitioners place undue emphasis on the First Circuit's citation to *Posadas de P.R. Associates v. Tourism, Co.*, 478 U.S. 328 (1986), in its analysis of the third prong of the *Central Hudson* test. The First Circuit cites *Posadas* only once, in rejecting one of the district court's suggested alternative measures: counter-detailing. Pet. App. 40 (citing *Posadas* in support of the statement: "It is not a ground for striking down a commercial speech regulation that some counter-informational campaign, regardless of the cost, might restore equilibrium to the marketplace of ideas"). The First Circuit did not conclude that it was "up to the legislature" to decide whether to achieve its interests through counter-detailing;

rather, the court found that measure to be infeasible "as a matter of simple economics."⁸ Pet. App. 39. The First Circuit's cite to *Posadas* does not "breathe life" into that aspect of the case that has been abrogated, and in any event, the brief reference to the case does not warrant review by this Court.

III. THE NATURE OF THE LOWER COURT DECISION MAKES THIS CASE A POOR VEHICLE FOR CERTIORARI

Even if the Court were otherwise to determine that the circumstances of this case raise some compelling issues, the nature of the First Circuit's decision makes this case a poor vehicle for resolving those questions. First, the court provided two grounds for its decision; therefore, should this Court grant certiorari, it cannot simply address the First Circuit's speech-conduct holding, but must also perform a *Central Hudson* analysis. Second, the First Circuit's dormant Commerce Clause ruling creates confusion over the scope of the PIL which complicates the First Amendment review. Third, issues of standing complicate this case due to the fact that PhRMA never filed suit in New Hampshire, yet PhRMA is attempting to bring its perspective into the case by filing an amicus brief. Fourth, the First Circuit restricted its

⁸ Given that pharmaceutical companies spend over \$4,000,000,000 annually on detailing, the First Circuit reasonably concluded that a program of counter-detailing by the State was not a feasible solution.

Central Hudson analysis to only one of New Hampshire's three asserted interests served by the PIL: cost containment. The State identified two other interests served by the PIL: maintaining patient and prescriber privacy, and protecting citizens' health from the adverse effects of skewed prescribing practices. This Court would either have to decide whether the regulation directly advances those interests without the benefit of the First Circuit's review, or remand for another round of proceedings. Finally, review of these issues is premature. Both Vermont and Maine have passed similar statutes which have been challenged on similar grounds. Given that the issues are pending in other cases and there is no direct split, there is no pressing need for a grant of certiorari at this time.



CONCLUSION

The petition for writ of certiorari should be denied.

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IN THE

Supreme Court of the United States

IMS HEALTH, INC. AND VERISPAN LLC,

Petitioners,

v.

KELLY A. AYOTTE, AS ATTORNEY GENERAL
OF THE STATE OF NEW HAMPSHIRE,

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the First Circuit

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REPLY BRIEF FOR THE PETITIONERS

1. The petition and the extraordinary *twelve* supporting *amicus* briefs filed by a diverse array of forty individuals and organizations demonstrate that certiorari should be granted to review the First Circuit's decision rejecting petitioners' First Amendment challenge to New Hampshire's Prescription Information Law (PIL). The decision below not only approves sweeping restrictions on the economically vital industry of data mining, but equally applies to any publication of commercially valuable facts, such as the stock reports of the *Wall Street Journal*. "In our 'information age,' sales and other voluntary transfers of data by and between businesses are fundamental to the efficient operation of the free enterprise system and often serve, as in this instance, societal needs as well as the interests of individual businesses." NELF et al. Br. 22.

New Hampshire's assertion that the ruling below "may not" extend far beyond data mining because the court of appeals characterized petitioners' transfers of prescription information as intended "to increase one party's bargaining power in negotiations" (BIO 13 (quoting Pet. App. 26)) is empty: any transfer of information that may facilitate better-informed decisions improves "bargaining power" in the identical sense. "If the state had barred the sale of Nielsen ratings to fast food advertisers to prevent them from targeting shows that appeal to young adults, there would be no doubt the restriction violated the first amendment, even though it did not directly regulate advertisers" (PhRMA & BIO Br. 6), but such a restriction would be free from First

Amendment scrutiny under the First Circuit's analysis.

Even if limited to prescription history information, the ruling below threatens a vast amount of speech, including "legitimate pharmaceutical survey research by eliminating a valuable information and data resource." Council of Am. Survey Research Orgs. et al. Br. 2. As the *amici* researchers explain: the PIL bans the transfer of "data describing real-world events and practices; data that informs researchers as they study and evaluate medical practices and health care policies—issues of vital interest to society, and information squarely within the core of constitutionally protected speech." Ernst Berndt, Ph.D. et al. Br. 5. The pernicious effect of the New Hampshire statute is well illustrated by the lead front-page article in the nation's largest newspaper announcing its list of the country's "Most Influential Doctors," which explains that "[b]ecause of the ban, no New Hampshire doctors appear." Steven Sternberg, et al., *In Patients' Hunt for Care, Database 'A Place to Start,'* USA Today, May 14, 2009, at 1A-2A.

2. The petition demonstrated (at 14-16) that the First Circuit's holding that the PIL regulates conduct rather than speech conflicts with this Court's precedents and with the rulings of other circuits. Indeed, since the petition was filed, the Tenth Circuit has reaffirmed the holding of *U.S. West, Inc. v. FCC*, 182 F.3d 1224 (10th Cir. 1999), that a prohibition on the use of data to target marketing is a speech restriction subject to First Amendment scrutiny. *Sorenson Communications, Inc. v. FCC*, No. 08-9503, 2009 WL 1561430 (10th Cir. June 4, 2009).

New Hampshire does not even attempt to defend the court of appeals' characterization of petitioners' speech as a "commodity." Through the PIL, "the State of New Hampshire is *not* regulating beef jerky – it is banning the flow of information *because* it may be used to persuade." Ass'n of Nat'l Advertisers Br. 9 (emphases in original). "Books, newspapers, magazines and website access are all forms of information sold as 'a commodity,' and certainly no State could regulate the transfer of these items without any First Amendment scrutiny." Source Healthcare Analytics Br. 6. *See also* Datamonitor Group Br. 7 ("The ultimate product—the speech at issue here—thus necessarily reflects considered judgments as to what the data means, which data is significant, and how it should be interpreted and conveyed to customers.").

Even assuming the First Circuit were correct that the PIL regulates "conduct," New Hampshire has no response to the petition's showing that the ruling below conflicts with this Court's precedents because the *purpose* of the regulation is to limit the speech of detailers, in violation of the First Amendment. *See* Pet. 19 (citing *United States v. O'Brien*, 391 U.S. 367, 377 (1968)).

3. The petition also demonstrated that certiorari is warranted because the court of appeals' alternative holding that the PIL survives First Amendment scrutiny conflicts with this Court's and other circuits' decisions.

a. The petition established (at 12-13) that the PIL rests on a prohibited paternalistic judgment that doctors cannot make correct decisions about what drugs to prescribe for their patients. New Hampshire only reinforces that fact: based on the Legislature's

view that "physicians are often unaware of the substantial impact manufacturer promotional activities have on their prescription practices" (BIO 2), the State determined to force "a *shift in the message* being provided by pharmaceutical representatives" (BIO 3 (emphasis added)). "A paternalistic desire to have consumers, let alone industry professionals, make different market choices among goods and services is not the type of interest that can sustain a restriction on truthful and non-misleading commercial speech." Coalition for Health Care Commc'ns Br. 16.

The State notes that it may seek to defend the PIL on two other grounds that the district court rejected and the First Circuit did not embrace: "maintaining patient and prescriber privacy, and protecting citizens' health from the adverse effects of skewed prescribing practices." BIO 35. But "[p]rivacy' considerations are phantoms" (Center for Democracy and Tech. et al. Br. 7) because (a) petitioners never receive identifying information about patients, and (b) doctors can have their own prescription information withheld or simply decline to meet with detailers. The State's remaining purported interest – inhibiting discussions with detailers that could lead doctors to make poor prescribing decisions – is "nothing more than a restatement of [the State's] contentions that the law can be justified because it prevents pharmaceutical companies from using prescriber-identifiable data in ways that undermine public health and increase health care costs" (Pet. App. 101, (Lipez, J.)) and thus is precisely the kind of paternalistic judgment that this Court's precedents reject. If New Hampshire wants to regulate the marketing or prescribing of

drugs, it should do so directly. Alternatively, it can (and does) engage in speech of its own. But the First Amendment does not allow it to suppress petitioners' constitutionally protected speech in a further effort to suppress the speech of pharmaceutical companies.

Nor does New Hampshire offer a persuasive defense of the First Circuit's standing holding. The petition demonstrated (at 28-29) that the court of appeals erred – and contravened this Court's decision in *Western States, supra* – in sustaining the PIL on the basis of the State's interest in "level[ing] the playing field" in communications between detailers and physicians (Pet. App. 25) while refusing to consider whether that interest was impermissibly paternalistic. The fact that the court of appeals permitted petitioners to "dispute[] the State's assertion that" the PIL would reduce health-care costs (BIO 28) only reinforces the point: there was no basis for the First Circuit to address whether the statute furthered the State's asserted interest while simultaneously refusing to consider whether that interest was even permissible under the First Amendment.

b. New Hampshire does not dispute the petition's showing (at 21-22) that there is a conflict in this Court's precedents over the definition of "commercial speech" that has spawned a significant circuit split. This case is an ideal vehicle to resolve that conflict because the information transfers prohibited by the PIL manifestly do not propose a commercial transaction or otherwise amount to advertising. See Pet. 23. The State's answer that "[t]his Court has been reluctant, for good reason, to reduce the doctrine to any simple rule or determinate criteria, and it should decline to do so now" (BIO 23 (footnote

omitted)) dramatically understates the pervasive uncertainty and inconsistency that exists in the law. Petitioners' point is not merely that the existing precedent is vague, but that it has produced *conflicting* standards that produce inconsistent results based on the coincidence of the court hearing the challenge.

The petition also presents an ideal opportunity for this Court to consider the degree of constitutional scrutiny applicable to restrictions on commercial speech. Petitioners' transfers of prescription information "have none of the characteristics associated with commercial speech": they "pose no 'risk of fraud,' . . . nor do they involve 'misleading, deceptive, or aggressive sales practices,' . . . that have in the past permitted more robust regulation of commercial speech." Am. Bus. Media et al. Br. 11-12. The PIL instead aims to suppress valuable exchanges between detailers and doctors that address the strengths and weaknesses of various treatments. Pet. 23-24 (quoting Pet. App. 32 and trial testimony).

c. New Hampshire offers no response to the petition's showing (at 26-27) that the PIL amounts to prohibited viewpoint discrimination. The statute's avowed purpose is to inhibit drug sales by brand-name manufacturers, while freely permitting the State and insurers to use the *identical* information to promote generic equivalents or state preferred brands. "In so doing, the government creates a bias in the democratic process designed to achieve the state's desired result, which is exactly the opposite of what the First Amendment is intended to do." PLF Br. 15.

d. The ruling below also creates a significant circuit conflict over the continued vitality of the

holding of *Posadas de P.R. Associates v. Tourism Co.*, 478 U.S. 328 (1986), that it is “up to the legislature’ to choose suppression [of speech] over a less speech-restrictive policy.” 44 *Liquormart v. Rhode Island*, 517 U.S. 484, 509 (1996) (plurality opinion calling for *Posadas*’ overruling). New Hampshire argues that the court of appeals cited *Posadas* only “in rejecting one of the district court’s suggested alternative measures: counter-detailing.” BIO 33. But that is precisely the point: the petition collected (at 36-37) numerous effective alternatives to the PIL. The First Circuit held, citing no other authority than *Posadas*, that the Legislature was free to choose to restrict petitioners’ speech instead. Pet. App. 40.

Relatedly, the petition demonstrated (at 30-31) that the First Circuit erred in “defer[ring] to the New Hampshire legislature” (Pet. App. 37), given that there is concededly “no direct evidence” (Pet. App. 33) of the statute’s efficacy. The Legislature thus made no study of whether the statute would work, never subpoenaed a single pharmaceutical provider for information about its detailing practices, never assessed whether doctors in the State were actually proscribing unnecessarily expensive drugs, and made no findings at all, much less findings that the law would achieve its objectives. In light of the First Amendment interests directly implicated by the PIL, the question whether the statute advances the State’s interests is not “more a matter of policy than of prediction.” *Contra* Pet. App. 35. Instead, the First Amendment obliges the courts to conduct a searching examination of the Legislative record that the PIL cannot possibly survive.

e. Certiorari is also warranted because the First Circuit sustained the PIL despite the fact that the

statute is patently under- and over-inclusive. See Pet. 34-37. The attorney general concedes that, under the First Circuit's authoritative construction of the PIL – which it adopted at the State's own urging – the statute will not significantly further the State's asserted interests "because pharmacies transmit the data to data centers *outside* of New Hampshire before selling the data to Petitioners." BIO 31-32 (emphasis in original). Having persuaded the court of appeals to adopt its prior construction in order to reject petitioners' Commerce Clause challenge, the State now attempts to reverse course to opine that "[t]he PIL need not be given such a narrow construction." BIO 32. This vacillation is entirely improper but ultimately academic. The Court's settled practice is to defer to the courts of appeals' interpretation of state law. See *McMillian v. Monroe County*, 520 U.S. 781, 787 (1997). There is accordingly no "confusion over the scope of the PIL." *Contra* BIO 34.

That is not to say that the PIL represents an insubstantial First Amendment burden. The statute continues to directly prohibit petitioners' acquisition and analysis of prescription history information provided by New Hampshire pharmacies that do not employ out-of-state data centers. The Attorney General's refusal to acknowledge that the State is bound by the court of appeals' construction of the PIL has furthermore created a *severe* chill in the willingness of even non-New Hampshire entities to provide prescription information to petitioners.

Nor is there merit to the State's assertion that "Petitioners' argument that the PIL is over-inclusive because it inhibits competition between patent-protected brands is unpersuasive since the PIL affects all brands equally." BIO 33. It is uncontested

that the PIL impedes detailing that would encourage the use of less expensive but equally effective brand-name drugs. The statute thus in many applications restricts speech that would further the State's asserted goals, which is the very definition of overinclusiveness. *See* Pet. 34-37.

4. New Hampshire's assertion that this case is not an ideal vehicle in which to resolve the questions presented is unpersuasive.

a. There is no reason to defer resolving the questions presented for several years until a pharmaceutical company can litigate a challenge to the PIL. *Contra* BIO 34. The resulting delay would harm significant First Amendment interests. There is no prospect that such a case would produce a different result, given that the First Circuit held that the PIL is immune from any First Amendment scrutiny. There also is no benefit to awaiting a suit instituted by a pharmaceutical company to decide the questions presented, given that the statute does not directly regulate them. New Hampshire's statement that the PIL imposes only "restrictions . . . on the *recipient's* use of the information" (BIO 17 (emphasis in original)) is a serious mischaracterization: the statute instead operates directly on *petitioners'* publication of information. *See* App. 13. "This case is a superior vehicle for addressing First Amendment issues implicated by the PIL" because Petitioners, as mere publishers of information, are entitled to greater First Amendment protection than drug advertisers. WLF et al. Br. 17.

b. Nor would a subsequent case produce a better record to decide the questions presented. As the First Circuit found, and New Hampshire reiterates, "[t]he raw facts are largely undisputed." BIO 30

(quoting Pet. App. 4). New Hampshire thus notably does not doubt that the record on the constitutionality of the PIL was fully developed.

Further, the many significant legal errors of the court of appeals are not tied to the underlying factual record. For example, the First Circuit held that (i) petitioners' speech warrants no First Amendment protection; (ii) the PIL alternatively restricts "commercial speech"; and (iii) the Court should defer to the New Hampshire legislature rather than scrutinize the law independently. None of those holdings relates in any respect to the record that was assembled in this case.

Amicus Vermont's effort (at 10-18) to tout the record in its own just-completed trial is misleading and merely represents a litigant's attempt to position its own case for review before this Court. Although proceedings in the New Hampshire litigation were placed on an expedited track by agreement of the parties, the trial was not conducted "very quickly." *Contra* Vermont Br. 9. During the half-year period between the filing of the complaint and the trial, the parties developed an extensive factual record. Petitioners' request for injunctive relief included seven declarations (including one detailing the entire legislative record). By the time of trial, the parties had conducted extensive discovery and recognized that they had compiled all the relevant facts. New Hampshire had deposed most of petitioners' trial witnesses (seven in total) and introduced declarations, depositions, and live testimony from an array of witnesses. Petitioners introduced deposition and trial testimony from six witnesses and articles and data on the uses of prescription histories. The trials in the New Hampshire and Vermont cases were

indistinguishable in length (both lasted five days); the only notable difference is that New Hampshire called *more* factual witnesses and introduced *more* evidence than did Vermont.

This suit is moreover a “facial challenge” (Vermont Br. 7) to the PIL only in the sense that petitioners filed suit prior to the statute’s enforcement. Vermont omits that petitioners’ complaint expressly seeks a declaration that the PIL “is unconstitutional, both facially *and as applied* to the non-commercial speech in which the plaintiffs engage.” D.E. 1, at 28 (emphasis added). In invalidating the PIL, the district court did not treat the suit as a facial attack. In any event, such pre-enforcement suits are commonplace in First Amendment cases, given the critical free speech interests involved. This Court has long applied an “exception to [the Court’s] normal rule regarding the standard for facial challenges” in such cases. *Virginia v. Hicks*, 539 U.S. 113, 119 (2003). Moreover, the ordinary concern with facial challenges – that the measure may constitutionally be applied to parties not participating in the suit – does not arise here because the parties agree (and even Vermont does not dispute) that the same First Amendment analysis applies to all applications of the PIL. Nor in the wake of the First Circuit’s ruling is there otherwise any disagreement about the circumstances in which the statute applies.

This Court’s intervention would also not in any respect be premature. The ruling below gives rise to significant conflicts with decisions of this Court and rulings of other circuits. Those are the prototypical grounds for certiorari review. The overwhelming volume and diversity of *amicus* participation

demonstrates the profound error and sweeping consequences of the ruling below. The question moreover arises in a context of undoubted importance, as two other states have already adopted similar statutory schemes and roughly half of the states are considering them.

CONCLUSION

For the reasons set forth above, as well as in the petition and the supporting *amicus* briefs, certiorari should be granted.

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BRIEF OF ACADEMIC RESEARCH
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BRIEF OF ACADEMIC RESEARCH SCIENTISTS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

INTEREST OF THE *AMICI CURIAE*¹

The *amici* are research scientists at leading academic research universities. They perform extensive research in numerous scientific fields. They rely for their research on basic data obtained from many different sources, including data from databases that are created for commercial purposes but which are made available to academic researchers at little or no cost because the database owners recognize the value inherent in such research. The *amici* include researchers who have utilized the specific commercial databases produced by IMS Health, Inc., one of the petitioners, for the purposes of conducting research and publishing results analyzing pharmaceutical practices in the United States. A list of the *amici* and their credentials appears in the Appendix.

SUMMARY OF ARGUMENT

The First Circuit's holding—and more profoundly, the First Circuit's reasoning—threatens the free flow of basic data information that is vital to society. In the most immediate sense, the First Cir-

¹ Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici* and their counsel made a monetary contribution to its preparation or submission. Counsel of record for all parties received notice at least 10 days prior to the due date of the intention of *amici* to file this brief. Petitioners have filed with this Court a blanket consent to *amici* participation. Respondent's communication consenting to the filing of this brief has been lodged with the Clerk's office.

cuit's holding and rationale threaten the free flow of information regarding medical prescription practices and health care. Beyond that, however, the holding and rationale threaten the free flow of a broad range of basic scientific, technical, sociological, and economic information. The First Circuit's decision empowers a state to interdict the free flow of information which is of enormous value to academic researchers, authors, policymakers, journalists, and the public, in two fundamentally objectionable ways.

The decision excludes from the ambit of First Amendment protection information that is gathered, synthesized, analyzed, and stored in large databases that are of use to a wide range of researchers on a virtually infinite array of subjects. This information, which should be properly understood as constitutionally protected speech, was demoted by the First Circuit to a mere commodity beneath the dignity of the First Amendment. The dissemination of this "commodity" was then transformed by the First Circuit from an exercise in the expression of speech to the mere performance of ordinary "conduct."

A large part of contemporary research in virtually all fields of intellectual endeavor—including science, technology, economics, business, law, education, sociology, and politics—involves the gathering, synthesizing, organizing, and analyzing of thousands, millions, or even billions of discrete transactions and events. This data is "crunched" for what it may illuminate or reveal, thereby advancing creativity and innovation in all realms of learning.

The analysis of such data is valuable in the aggregate, for what it may reveal about large patterns and trends, and in the particular, for what it may reveal about specific actors or enterprises. The produc-

tion and use of such data serves all of the worthy purposes that animate the First Amendment's protection of the free flow of information, including the advancement of discovery and invention, the free play of the marketplace of ideas, and the service of transparency and accountability.

The decision below also threatens the free flow of information by permitting the government to transform otherwise constitutionally protected speech into an unprotected "commodity" merely because the speech is sold for a commercial purpose, thereby eliminating the commercial incentive to gather and make available to the marketplace information of great value. By eliminating the economic incentive to engage in the labor-intensive task of gathering and organizing such information and making it available in databases for sale in the marketplace, the First Circuit's ruling strongly diminishes the likelihood that such databases will be created at all. Academic researchers thus would be deprived of access to this information, which is often made available by the producers of such databases to academic researches at little or no cost.

The underlying data at issue here is not properly understood as "commercial speech." Rather, it is scientific and medical information produced for profit motive. Speech does not become "commercial speech," with diminished constitutional protection, merely because it is produced and sold for profit, any more than speech *about commerce* is commercial speech.

Regardless of whether the underlying information here is treated as speech receiving full First Amendment protection or as commercial speech, however, the sole interest advanced by New Hampshire and the First Circuit to justify the speech

ban—reduction of health care costs—is insufficient as a matter of law to justify the speech restriction. That justification is simply too weak and too attenuated to sustain a regulation on any theory other than mere “rational basis” review, which is inappropriate here. Whatever brand of speech New Hampshire’s law may regulate, it surely is regulating speech. Accordingly, the restriction must receive either strict scrutiny or intermediate scrutiny. Under either standard of review, the law must fail.

At its core, the New Hampshire law is an exercise in paternalism. The law is grounded in the assumption that doctors exposed to the marketing practices of pharmaceutical detailers who are aware of the doctors’ past prescribing habits will be persuaded to make bad prescription decisions when treating patients. The indulgence of this paternalistic assumption is constitutionally forbidden.

ARGUMENT

I. BASIC DATA IS VALUABLE INFORMATION DESERVING OF FULL FIRST AMENDMENT PROTECTION

A. The Importance of Basic Data

Researchers such as the *amici* have a powerful interest in fighting the pernicious effects of any regulation that empowers the government to treat information as contraband. The First Circuit’s decision allows New Hampshire to do exactly that. By targeting information related to medical prescriptions and health care practices, such a regulation menaces the free flow of basic data relevant to a vast array of subjects, thereby exerting a chilling effect on research in

science, technology, economics, business, law, education, sociology, and politics.

The First Circuit's opinion treated the information gatherers and publishers in this litigation dismissively, characterizing them pejoratively as "data miners." Pet. App. 3. The First Circuit's opinion also treated the information itself pejoratively, describing it as an ordinary article of commerce, a commodity akin to beef jerky. *Id.* at 23 ("The plaintiffs, who are in the business of harvesting, refining, and selling this commodity, ask us in essence to rule that because their product is information instead of, say, beef jerky, any regulation constitutes a restriction of speech."). This mindset permeated the opinion below, leading the First Circuit to hold initially that the New Hampshire law did not regulate constitutionally protected speech *at all*, and thus triggered no heightened First Amendment scrutiny of any kind. *Id.* at 19 ("[W]e nonetheless believe that what the state seeks to regulate here is conduct, not expression.").

To academic researchers, authors, and journalists, the data produced by information providers such as the petitioners is not a "commodity." Nor is it "commercial speech." It is data describing real-world events and practices; data that informs researchers as they study and evaluate medical practices and health care policies—issues of vital interest to society, and information squarely within the core of constitutionally protected speech.

Commercial databases such as those compiled by petitioner IMS Health often have unique value to the academic world because they provide a broad, unbiased view of data that is not available from smaller or noncommercial databases. The IMS Health databases, for example, include collections of prescription

information relating to all prescriptions, without regard to the identity of the entity paying for the prescription. Other databases, such as those maintained by Medicare and Medicaid agencies, or the claims databases of individual insurers, provide only incomplete information that can lead to erroneous conclusions.

For example, IMS Health's data has been used in research into physician-prescribing patterns in underserved urban areas to determine patterns of undertreatment of patients with asthma; in a pediatric study on the use of antibiotics to assess the impact of patient and clinician education on antibiotics; and in many other non-commercial scientific or academic projects. The importance of this research is underscored by the fact that it has been funded by grants from the federal government. See Surrey M. Walton, et al., *Prioritizing Future Research on Off-Label Prescribing: Results of a Quantitative Evaluation*, 28 PHARMACOTHERAPY 1443 (2008) (results of federally funded research based on data obtained from an IMS Health database that provided ongoing estimates of drug prescribing practices of office-based physicians in the United States). Such studies have in turn been cited in mainstream media reports on drug prescribing practices. All of this research is jeopardized by the First Circuit decision.

B. The New Hampshire Law Regulates Fully Protected Speech, Not Conduct

The attempt by the First Circuit to convert information into a commodity, and in turn to convert the publication of speech into mere conduct, cannot be squared with established First Amendment doctrine. The regulation of "speech" is *never* simply the regulation of "conduct" when the *justification for the*

law is grounded in the perceived harm that will be caused by the content of the message. See, e.g., *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989) (regulation is content-neutral only if it is "justified without reference to the content of the regulated speech"). See also *Clark v. Community for Creative Non-Violence*, 468 U.S. 288, 295 (1984).

C. Basic Data Is Entitled to Full First Amendment Protection

The underlying data at issue here is information entitled to the *full* protection of the First Amendment, protection that is routinely extended to a wide range of information on matters relating to science, politics, economics, religion, or culture. The protections of the First Amendment "are not confined to any field of human interest." *United Mine Workers v. Ill. State Bar Ass'n*, 389 U.S. 217, 223 (1967). As this Court has recognized, "[f]reedom of discussion, if it would fulfill its historic function in this nation, must embrace all issues about which information is needed or appropriate to enable the members of society to cope with the exigencies of their period." *Thornhill v. Alabama*, 310 U.S. 88, 102 (1940). Under the First Amendment it is immaterial whether matters "sought to be advanced * * * pertain to political, economic, religious or cultural matters." *NAACP v. Alabama*, 357 U.S. 449, 460 (1958).

Speech is speech; information is information; speakers are speakers; information providers are information providers. First Amendment protection cannot be avoided by the mere manipulation of labels, so that information is dismissed as mere "data" and then further dismissed as a mere "commodity." To dismiss those who gather, organize, synthesize, and analyze data, packaging it and presenting it to

the marketplace, as mere "data miners" does not make their status as speakers or their speech "entirely invisible to the Constitution." *R.A.V. v. City of St. Paul*, 505 U.S. 377, 383 (1992).

To the contrary, many researchers, academics, authors, and journalists are "data miners," in the sense that they gather raw information, sort and categorize and organize it, and then package and market it in forms useful to information consumers. Their activities fall well within the core protections of the First Amendment. Business journalists writing in-depth about the performance of publicly traded companies, sports journalists writing about the earned-run averages of baseball pitchers, real estate journalists writing about trends in housing sales or mortgage rates, education journalists writing about the test scores of students, political journalists writing about the voting patterns of different precincts in a state presidential primary—all these people laboriously gather and analyze raw data and then present that data to the marketplace.

Basic data is also the essential stuff of basic science. There is no loophole in First Amendment relieving government of its constitutional obligations to avoid the abridgment of speech merely because the information is pure data. See *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 762 n.8 (1985) (plurality opinion); *Id.* at 787 (Brennan, J., dissenting); *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446-447 (2nd Cir. 2001) (the First Amendment protects "[e]ven dry information").

The gathering and analysis of basic data serves the marketplace of ideas in both its aggregate and specific forms. Basic data is valuable in the aggregate for what it may reveal about large patterns and

trends. Basic data is valuable in the particular for what it may reveal about specific actors or enterprises. The production and use of such data serves the vital purposes that animate the First Amendment's protection of the free flow of information, including the advancement of discovery and invention, the free play of the marketplace of ideas, and the service of transparency and accountability.

II. THE INFORMATION BANNED BY THE NEW HAMPSHIRE LAW IS NOT COMMERCIAL SPEECH

A. The Constitutional Meaning of Commercial Speech

As a secondary and alternative theory, the First Circuit held that, at most, the information at issue in this case was "commercial speech," deserving only the intermediate scrutiny applicable under *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), and its progeny.

This Court has not yet clearly defined what is meant by "commercial speech." In *Nike, Inc. v. Kasky*, 539 U.S. 654 (2003), the Court dismissed a writ of certiorari as improvidently granted in a case that might have helped clarify that term. Among the reasons supporting a grant of certiorari in this case is the extremely pernicious impact of the First Circuit's alternative holding that would treat the pharmaceutical data banned by the New Hampshire law as commercial speech.

This Court has generally confined "commercial speech" to advertising or marketing activity, speech "that does no more than propose a commercial transaction." *United States v. United Foods, Inc.*, 533 U.S.

405, 409 (2001); *Bd. of Trustees v. Fox*, 492 U.S. 469, 473-474 (1989). The Court has at times suggested a modestly broader definition, treating "commercial speech" as "expression related solely to the economic interests of the speaker and its audience." *Cent. Hudson*, 447 U.S. at 561.

B. Commercial Speech Should Not Be Conflated with Commercial Purpose

Regardless of whether this Court eventually decides that the appropriate definition of commercial speech should be narrower or broader than advertising and marketing in the classic sense, the treatment of the basic data at issue here as commercial speech would work great mischief for all of First Amendment law, reversing the settled principle that the mere existence of a *commercial motive* or the use of speech for a *commercial purpose* does not render the speech itself "commercial speech." Companies such as petitioners serve as information middlemen. They advance the free flow of information by gathering and synthesizing data and then selling that data to those who find it valuable. As such, they are not conceptually different from mainstream media companies that gather raw data and package it for commercial consumption, enterprises that operate for profit but that have always been understood as falling within the core purpose and protection of the First Amendment.

A law preventing the *Wall Street Journal* from harvesting raw data from corporate reports and packaging that data to sell it for "commercial purposes," for example, would plainly violate the First Amendment. The stock transactions reported by the *Wall Street Journal*, whether reported in aggregate form to present conclusions about large economic

trends or presented in highly specific form to analyze the past performance of specific economic players, is understood as *speech* protected by the First Amendment. More than that, such data is understood as speech *about commerce*, but not itself *commercial speech*. The fact that data has value in the marketplace and can be bought and sold does not render it a "commodity" that is something less than speech. And the fact that the speech might be exploitable for a "commercial purpose" by investors, stock advisors, marketers, and advertisers does not render the *data itself* "commercial speech."

If this is true of the *Wall Street Journal* reporting on economic transactions, *Sports Illustrated* reporting on baseball, or *USA Today* reporting on presidential politics, then it is also true of the myriad specialized information providers who gather and sell information in niche markets to willing buyers with specialized interests and needs.

In all of these examples, the Constitution is agnostic as to whether the motivation to gather and disseminate the speech is driven in whole or in part by profit. This Court has repeatedly admonished that constitutional protection of speech is not diminished merely because the speech is sold for commercial gain. "Speech * * * is protected even though it is carried in a form that is 'sold' for profit." *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761 (1976). See also *Buckley v. Valeo*, 424 U.S. 1 (1976); *Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376 (1973); *N.Y. Times Co. v. Sullivan*, 376 U.S. 254 (1964); *Smith v. California*, 361 U.S. 147 (1959); *Joseph Burstyn, Inc. v. Wilson*, 343 U.S. 495 (1952); *Murdock v. Pennsylvania*, 319 U.S. 105 (1943).

Our constitutional tradition treats the marketplace of ideas and the marketplace of commerce not as antagonistic but as complementary. Our entire tradition of intellectual property protection, itself enshrined in the Copyright and Patent Clauses, for example, is grounded in the supposition that the economic incentive created by intellectual property protection enhances the marketplace of ideas. See U.S. Const. art. I, § 8, cl. 8 ("Congress shall have power * * * To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."); *Eldred v. Ashcroft*, 537 U.S. 186 (2003).

III. THE COST REDUCTION INTERESTS ADVANCED BY THE STATE ARE INSUFFICIENT TO JUSTIFY THE SPEECH BAN UNDER ANY STANDARD OF FIRST AMENDMENT REVIEW

A. The New Hampshire Law Fails Any First Amendment Standard

The sole interest advanced by New Hampshire and the First Circuit to justify the speech ban is the reduction of health care costs. This interest is insufficient, as a matter of law, to justify the speech restriction. The justification proffered by New Hampshire is simply too weak and too attenuated to sustain a regulation on any theory other than mere "rational basis" review. Whatever brand of speech New Hampshire's law may regulate, it surely is regulating speech, thereby triggering either strict scrutiny or intermediate scrutiny review. Under either standard of review, the law must fail.

B. Cost Reduction Will Not Justify the Law Under Strict Scrutiny Review

This Court has acknowledged that there may be rare occasions in which compelling governmental interests justify restrictions on the dissemination of truthful information, such as the protection of national security secrets, individual privacy, or intellectual property. See *Near v. Minnesota ex rel. Olson*, 283 U.S. 697, 716 (1931) ("No one would question but that a government might prevent * * * publication of the sailing dates of transports or the number and location of troops"); *Florida Star v. B.J.F.*, 491 U.S. 524 (1989) (accepting as an interest of the highest order the protection of the privacy of a rape victim's identity); *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539 (1985) (rejecting the argument that the First Amendment gave a magazine the right to infringe copyright through the unauthorized publication of material from a not-yet released autobiography of President Ford).

Even when interests proffered by the government to justify the banning of information have been recognized by this Court as potentially compelling in principle, however, this Court has in practice almost always struck down such regulation. The Court has typically found that the actual vindication of the interest offered by the government was speculative, or that the law was not narrowly tailored to accomplish the objective. See, e.g., *Bartnicki v. Vopper*, 532 U.S. 514 (2001) (holding that the First Amendment barred imposition of liability for the publication by the media of illegally intercepted private phone conversations when the media outlets were not themselves complicit in the interception and did not know the source of the material); *Butterworth v. Smith*,

494 U.S. 624 (1990) (refusing to enforce the traditional veil of secrecy surrounding grand jury proceedings against a reporter who wished to disclose the substance of his own testimony after the grand jury had terminated, holding the restriction inconsistent with the First Amendment principle protecting disclosure of truthful information); *Florida Star*, 491 U.S. 524 (1989) (holding unconstitutional the imposition of liability against a newspaper for publishing the name of a rape victim in contravention of a Florida statute prohibiting such publication in circumstances in which a police department inadvertently released the victim's name); *Smith v. Daily Mail Publ'g Co.*, 443 U.S. 97, 104 (1979) (finding unconstitutional the indictment of two newspapers for violating a state statute forbidding newspapers to publish, without written approval of the juvenile court, the name of any youth charged as a juvenile offender, where the newspapers obtained the name of the alleged juvenile assailant from witnesses, the police, and a local prosecutor, and stating that the "magnitude of the State's interest in this statute is not sufficient to justify application of a criminal penalty"); *Landmark Communications, Inc. v. Virginia*, 435 U.S. 829 (1978) (overturning criminal sanctions against a newspaper for publishing information from confidential judicial disciplinary proceedings leaked to the paper).

No interests of comparable gravity are implicated here. The data describing prescription practices is "patient-anonymized," meaning that no patients are identified and no privacy rights are implicated. The *only* interest identified by the opinion below as support for the New Hampshire Law—the hypothesis that the law will reduce health care costs by hampering the effectiveness of detailers who market phar-

maceuticals to doctors—comes nowhere close to the level of importance that would justify an abridgment of speech and cannot satisfy the demanding fit between means and ends that is required to satisfy the narrow tailoring requirement imposed by strict scrutiny review. By the First Circuit's own admission, there was no direct evidence that the New Hampshire law would lower health care costs, and what little showing there was "that health care costs would lessen should prescriber histories be denied to detailers was not overwhelming." Pet. App. 33.

C. The Analysis Below Was "Rational Basis by Any Other Name"

Conceding that New Hampshire had little evidence to support its cost-reduction claims, the First Circuit speculated that the lack of evidence could be attributed to the fact that New Hampshire was the first state to enact such a law and ought not to be penalized for being the first to give it a try. Pet. App. 35-36.

The notion that courts should defer to social policy experimentation by legislatures is a well established principle of constitutional law when applying the minimal rational basis standard of review applicable to ordinary economic and social legislation. See *Fitzgerald v. Racing Ass'n of Cent. Iowa*, 539 U.S. 103, 107 (2003). In that arena, "reform may take one step at a time, addressing itself to the phase of the problem which seems most acute to the legislative mind." *Williamson v. Lee Optical of Okla., Inc.*, 348 U.S. 483, 489 (1955). In such cases the government need have only a "plausible policy reason for the classification." *Nordlinger v. Hahn*, 505 U.S. 1, 11 (1992).

This was the standard that once applied to the regulation of commercial speech, when it was still deemed outside the protection of the First Amendment. See *Valentine v. Chrestensen*, 316 U.S. 52 (1942); *Railway Express Agency v. New York*, 336 U.S. 106 (1949). But it is the law no longer. Under any form of heightened First Amendment review—whether it is the strict scrutiny test applicable to content-based regulation of speech, or the intermediate level of scrutiny afforded commercial speech under *Central Hudson* and its progeny—the one-step-at-a-time approach of rational-basis deference is not appropriate. The Constitution does not give New Hampshire a free pass merely because it is the first out of the gate with a bad law.

New Hampshire turned the First Amendment on its head. “If the First Amendment means anything, it means that regulating speech must be a last—not first—resort. Yet here it seems to have been the first strategy the Government thought to try.” *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002).

The First Circuit’s dismissive attitude toward the medical prescription information subject to the state’s ban initially caused it to hold that the speech being regulated was entitled to no First Amendment protection at all. This same attitude infiltrated and poisoned its commercial speech analysis. While purporting to apply *Central Hudson*, the decision was rational basis review in disguise. The First Circuit’s application of *Central Hudson* was not the serious and searching analysis of commercial speech that has evolved in this Court over the past three decades, but rather a pallid version of *Central Hudson* that effectively demoted the standard of review to little more than a rational basis test, as if the informa-

tion at issue was not to be taken seriously as speech worthy of any true First Amendment protection. This blind spot clouded the First Circuit's analysis, causing it to fail to properly perceive that the entire cost-reduction hypothesis was steeped in paternalism.

The trajectory of modern commercial speech law is impressive in its manifest hostility toward paternalism. Paternalism is the enemy of the First Amendment. See, e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554-555 (2001) (striking down some and sustaining some restrictions on tobacco advertising); *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173 (1999) (striking down casino gambling advertising limitations); *44 Liquor Mart, Inc. v. Rhode Island*, 517 U.S. 484, 497, 503 (1996) (striking down liquor advertisement restrictions, noting "a State's paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it. * * * [B]ans against truthful, nonmisleading commercial speech * * * usually rest solely on the offensive assumption that the public will respond 'irrationally' to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good"); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (striking down beer advertising regulations); *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 147 (1994) (striking down restrictions on accountancy advertising); *Edenfield v. Fane*, 507 U.S. 761 (1993) (striking down commercial speech limitations on accountants); *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993) (striking down restrictions on newsracks for commercial flyers and publications); *Peel v. ARDC of Ill.*, 496 U.S. 91 (1990)

(regulation banning lawyer advertisement of certification by the National Board of Trial Advocacy as misleading was unconstitutional); *Shapero v. Ky. Bar Ass'n*, 486 U.S. 466 (1988) (regulation banning solicitation for legal business mailed on a personalized or targeted basis to prevent potential clients from feeling undue duress to hire the attorney unconstitutional); *Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626 (1985) (striking down some and upholding some restrictions on lawyer advertising); *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983) (statute banning unsolicited mailings advertising contraceptives to aid parental authority over teaching their children about birth control unconstitutional); *In re R.M.J.*, 455 U.S. 191 (1982) (regulations limiting the precise names of practice areas lawyers can use in ads and identifying the jurisdictions lawyer is licensed in as misleading unconstitutional); *In re Primus*, 436 U.S. 412 (1978) (striking down restrictions on solicitation of legal business on behalf of ACLU); *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977) (regulation banning lawyer advertisement of prices for routine legal services as misleading unconstitutional); *Linmark Assocs., Inc. v. Township of Willingboro*, 431 U.S. 85 (1977) (regulation banning placement of "for sale" signs in the front lawns of houses in order to prevent the town from losing its integrated racial status unconstitutional); *Va. State Bd. of Pharmacy*, 425 U.S. 748 (1976) (striking down restrictions on pharmaceutical advertising); *Bigelow v. Virginia*, 421 U.S. 809 (1975) (striking down restrictions on abortion advertising).

Many doctors find the information provided by detailers regarding their prescribing habits useful, because they gain insight or new knowledge from the

information that detailers provide. Some doctors appreciate the free samples of new products that often accompany such visits, which they pass on to patients. Others simply will have nothing to do with detailers, because they find the practice unethical or distasteful. Doctors are not children—they can fend for themselves in making these choices.

In *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), the Court held that provisions in the Food and Drug Modernization Act of 1997 that restricted physicians and pharmacists from advertising compounding drugs violated the First Amendment. The Court refused to make the “questionable assumption that doctors would prescribe unnecessary medications” and rejected the government’s argument that “people would make bad decisions if given truthful information about compounded drugs.” *Id.* at 374. Indeed, the entire arc of this Court’s modern commercial speech jurisprudence is against “the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.” *Ibid.* (citing *Va. State Bd. of Pharmacy*, 425 U.S. at 769).

The Constitution allows advertisers to proclaim that seven out of ten doctors prefer “brand x,” just as it allows politicians to proclaim that seven out of ten voters favor “position y.” More pointedly, the Constitution protects the right to disseminate data about the particular prescribing habits of a specific doctor, just as it protects the right to disseminate data about the particular voting patterns of a specific candidate. The presumption of the First Amendment is that the

free flow of information facilitates quality decision-making and enhances accountability.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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APPENDIX

APPENDIX

The *amici curiae* are as follows¹:

Ernst R. Berndt, Ph.D., is the Louis E. Seley Professor in Applied Economics at the MIT Sloan School of Management and Co-Director of the Harvard-MIT Biomedical Enterprise Program. In the last decade, much of Professor Berndt's research has focused on economic issues in health care, with a strong emphasis on measurement of costs, outcomes, and prices. He serves as Director of the National Bureau of Economic Research Program on Technological Progress and Productivity Measurement, and until recently was Chair of the Federal Economic Statistics Advisory Committee, an interagency committee formed by the Bureau of Labor Statistics, the Bureau of Economic Analysis, and the U.S. Census Bureau. He also served as a member of the National Science Foundation Panel on Measurement, Methodology, and Statistics. Currently he serves on the Editorial Board of *Health Affairs*. Professor Berndt's health care research has been published in peer-reviewed journals such as the *New England Journal of Medicine*, *American Journal of Psychiatry*, *Journal of Mental Health Policy and Economics*, *Journal*

¹ This brief reflects the views of the *amici* professors as individuals, and may or may not reflect the views of their institutions. The names of their institutions are included only for identification purposes. The *amici* have joined in this brief due to their concern that important information that is made available to them by commercial data providers such as petitioners may no longer be available if prohibitions on commercial use of the information are allowed to stand. The legal analysis herein is that of their counsel.

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**In The
Supreme Court of the United States**

IMS HEALTH , INC., AND VERISPAN LLC,
Petitioners,

v.

KELLY M. AYOTTE, as Attorney General
of the State of New Hampshire,
Respondent.

**On Petition for a Writ of Certiorari to the
United States Court of Appeals for the First
Circuit**

**BRIEF AMICUS CURIAE OF AMERICAN
BUSINESS MEDIA; THE CONSUMER DATA
INDUSTRY ASSOCIATION; FIRST ADVANTAGE
SAFERENT, INC; THE NATIONAL ASSOCIATION
OF PROFESSIONAL BACKGROUND SCREENERS;
REED ELSEVIER INC.; AND THE SOFTWARE &
INFORMATION INDUSTRY ASSOCIATION IN
SUPPORT OF PETITIONER**

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Interest of the Amici*

Amici collect, aggregate and publish databases containing truthful information acquired from public records and other lawful sources. Their products include databases such as LexisNexis, which contains news articles, case law, statutes, and public records used by lawyers, business professionals, and journalists, and App Alert, a specialized collection of lawfully collected information used to inform landlords and employers whether a prospective tenant or employee has outstanding warrants. *Amici* file this brief because of the First Circuit's apparent conclusion (1) that the aggregation, compilation and publication of lawfully acquired truthful information for commercial purposes is "conduct," not "speech," and (2) that, if that activity is protected speech, it is not fully protected speech, but is entitled only to the more limited protection accorded by the Constitution to "commercial" speech. These conclusions are clearly incorrect and will, unless reversed, seriously threaten the ability of *amici* and others to provide accurate information services to the public.

American Business Media is a not-for-profit association serving business-to-business information providers. Its 236 members currently produce 1,500

* No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, their counsel, or their members, made a monetary contribution to its preparation or submission. The parties were notified of *amici's* intention to file more than ten days before the date that this brief was due, and they have consented to its filing via consent lodged with the Clerk of this Court.

business and professional periodical publications such as *Oil and Gas Journal*, *Prairie Farmer*, and *Computer World*.

The Consumer Data Industry Association is an international trade association of more than 500 companies that publish databases containing consumer credit and other information used to prevent fraud, assess credit risk, evaluate prospective employees and tenants, locate witnesses, apprehend fugitives, and locate non-custodial parents.

First Advantage SafeRent compiles and maintains a database of public record filings of landlord tenant court proceedings and criminal history records obtained from public records and/or government agencies, and provides consumer reports to clients for tenant screening purposes. It also furnishes both criminal history reports and credit reports obtained from the main nationwide credit bureaus, Equifax, Experian and Trans Union, to the multifamily housing industry for employment and tenant screening purposes.

The National Association of Professional Background Screeners represents over 600 pre-employment background screening firms across the United States. Its members provide pre-employment background screening information to employers and the managers of apartment buildings in every state, who use that information to decide whether or not to extend a job offer or to rent an apartment.

Reed Elsevier Inc. and its several business units collect and aggregate public record and other information for a large number of commercial, educational, and governmental purposes. Their

products, such as LexisNexis, which has more than 3.6 million private and governmental subscribers, contain databases of judicial opinions, local, state and federal statutes and regulations, bankruptcy filings, property-title records and liens, and tax assessor records.

The Software & Information Industry Association is a trade association of software creators and information providers. Its approximately 500 member companies publish databases, and related software tools used by researchers, journalists and business professionals.

REASONS FOR GRANTING THE PETITION

The First Circuit's Holding That Commercial Publishing of Informational Databases Enjoys Either No, or Reduced, First-Amendment Protection Raises Questions of National Importance.

As the author of the majority opinion below correctly understood, this case "raises important constitutional questions that lie at the intersection of free speech and cyberspace." *IMS Health v. Ayotte*, 550 F.3d 42, 44 (1st Cir. 2008). *Amici* and others have invested billions of dollars in the creation, organization, and publication of easily searchable databases that make large quantities of accurate, useful and often essential information available to private and governmental users. The information in these databases is used for a variety of beneficial and important purposes, including legal and scientific research, risk analysis, and detection of

fraud. These publications fulfill the promise of the digital age by facilitating the acquisition of accurate information in efficient, complete and user-friendly ways.

The First Circuit has held that, for purposes of constitutional analysis, the information in these databases is a "commodity," the publication of which is "conduct" rather than constitutionally protected speech, thereby completely depriving the publication of the information of First Amendment protection. In the words of the majority opinion below:

We say that the challenged elements of the Prescription Information Law principally regulate conduct because those provisions serve only to restrict the ability of data miners to aggregate, compile, and transfer information destined for narrowly defined commercial ends. In our view, this is a restriction on the conduct, not the speech, of the data miners. ... In other words, this is a situation in which information itself has become a commodity. The plaintiffs, who are in the business of harvesting, refining, and selling this commodity, ask us in essence to rule that because their product is information instead of, say, beef jerky, any regulation constitutes a restriction of speech. ... We believe that ... New Hampshire has adopted a form of conduct-focused economic regulation that does not come within the First Amendment's scope.

IMS Health, 550 F.3d at 53-54.

In the alternative, the opinion below has held that, "[i]f speech at all" these publications constitute "commercial speech," that receives, at most, the protection offered by "intermediate" constitutional scrutiny. *See id.* at 54.

In reaching these two conclusions, the Court below committed the critical error of denying full constitutional protection to the aggregation and publication of lawfully acquired, truthful information because of the way in which that information is used by those to whom it is communicated. That approach is wrong and constitutes an extremely dangerous threat to First Amendment values. The compelling reasons for giving special constitutional protection to speech apply at least as strongly to publications containing accurate factual information as they do to any other constitutionally protected publication. If truthful information is used for improper or criminal purposes, the proper (and constitutionally required) course is to regulate or prohibit the unacceptable or criminal conduct, not to censor the public's access to truthful, lawfully acquired, and useful information.

I. The Publication of Lawfully Acquired Truthful Information is Constitutionally Protected Speech, Not "Conduct."

Section 318:47-f of the New Hampshire Statutes prohibits the petitioners in this case from "transferring," "using" or "selling" legally obtained,

truthful information because recipients of the information use the information for the purpose of promoting commercial products.¹ N.H. Rev. Stat. Ann. § 318:47-f. Section 318:47-f clearly bans speech protected by the First Amendment: "If the acts of 'disclosing' and 'publishing' information do not constitute speech, it is hard to imagine what does fall within that category... ." *Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001) (internal quotation omitted). That protection is not lost because the information is used by one or more of its recipients for an improper or even illegal purpose. See, e.g., *Fla. Star v. B. J. F.*, 491 U.S. 524, 538 (1989) (holding it unconstitutional to prohibit the media from communicating an alleged rape victim's identity because some might use the information to harass the victim); *Smith v. Daily Mail Pub. Co.*, 443 U.S. 97, 104 (1979) (holding unconstitutional a state statute prohibiting the publication of the name of a juvenile offender on the basis that employers will refuse to hire him); *Carey v. Population Servs. Int'l*, 431 U.S. 678, 700-701 (1977) (finding that the fact that teens might engage in sexual activity is not a basis for banning the advertising of contraceptives);

¹ Section 318:47-f of New Hampshire's statutes outlaws any "electronic transmission intermediary" or "similar entity" from "selling, transferring, or using" physician-identifiable information for any non-exempted commercial purpose. N.H. Rev. Stat. Ann. § 318:47-f. Under the statute, "commercial purpose" includes not only "advertising, marketing or promotion," but also "any activity that *could be used* to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing task force." Thus, although ostensibly directed at pharmaceutical sales practices, the statute's reach is substantially broader.

Cox Broadcasting Corp. v. Cohn, 420 U.S. 469, 496 (1975) (holding unconstitutional a state statute barring release of a rape victim's identity because of the effect on privacy). Similarly, information does not become a commodity—like “beef jerky,” as the court below put it—because of the way in which it is used by those to whom it is communicated. If a state wishes to prohibit or regulate what it believes to be a misuse of truthful information, the First Amendment requires that it regulate that misuse directly, rather than censoring the collection and communication of the information so as to make it unavailable to everyone. “It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.” *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 770 (1975).² The First Circuit's decision that the information collected, organized and communicated by the plaintiffs in this case becomes a commodity, rather than protected speech because it is used for a commercial purpose is flatly inconsistent with these well-established principles.

² The First Circuit invoked this Court's cases, holding First Amendment protection inapplicable to conduct, such as “agreements in restraint of trade, communications in furtherance of crimes, or statements or actions creating hostile work environments, and promises of benefits made by an employer during a union election.” *IMS Health*, 550 F.3d at 52 (internal citations omitted). These cases are inapposite. They deny First Amendment protection because the prohibited speech *itself* is criminal. *E.g.*, 15 U.S.C. § 1 (preventing anti-competitive activity through agreements in restraint of trade); 15 U.S.C. § 158 (prohibiting unfair labor practices through including employer interference with the right to organize).

Full First Amendment protection for the collection and publication of truthful information is essential in a democratic society. The freedom to publish accurate, lawfully acquired information is "of critical importance to our type of government in which the citizenry is the final judge of the proper conduct of public business." *Cox Broadcasting*, 420 U.S. at 495. That freedom applies not only to the publication of public records, which "by their very nature are of interest to those concerned with the administration of government," *id.* at 495, but also to information acquired through "routine newspaper reporting techniques." *Daily Mail*, 443 U.S. at 103.

Since the *Daily Mail* decision, the information demands of both government and private industry have become increasingly complex. The ability to provide that information is greatly enhanced by the use of digital technology. *Amici* collect public record and other information by querying businesses, visiting courthouses and other record depositories, and interviewing private parties and public officials. The information thus collected is invaluable for many purposes: for example, *amicus* American Business Media's city business journals compile, organize and publish extensive useful information about local businesses – lists of the largest public and private companies, the largest employers, the fastest growing companies, etc. These compilations enable the public to obtain information about their communities, which groups, individuals, governments and businesses would never be able to obtain on their own.

These aggregate sources of information create enormous efficiencies for almost any kind of

research. Instead of searching the records of every local public records custodian, or having to survey individual businesses about their activities, journalists, law enforcement agencies, or law firms and others may use comprehensive databases obtain prompt, up-to-date information for a variety of important purposes such as investigating political corruption, screening job applicants, locating parents who default on child support obligations, or verifying that borrowers have sufficient assets to collateralize a loan. Databases can be "mined" in order to locate witnesses, confirm the validity of professional licenses, assist in fraud prevention, or locate blood, bone marrow or other organ donors. Informational databases are frequently used by the government itself.

For example, in 1999, FBI Director Louis Freeh testified that:

The FBI subscribes to various commercial on-line databases, such as Lexis/Nexis, Dun & Bradstreet, and others, to obtain public source information regarding individuals, businesses, and organizations that are subjects of investigations. Information obtained includes credit records, real property and tax records; boat, plane, and motor vehicle registration records; business records.... In 1998, more than 53,000 inquiries were made of these databases. Information from these inquiries assisted in the arrests of 393 fugitives wanted by the FBI, the identification of more than \$37 million

in seizable assets, the locating of 1,966 individuals wanted by law enforcement, and the locating of 3,209 witnesses wanted for questioning. Over 97 percent of the inquiries made produced new investigative information for follow-up action by agents and investigators. Subscription to these databases allows FBI investigative personnel to perform searches from computer workstations and eliminates the need to perform more time consuming manual searches of federal, state, and local records systems, libraries, and other information sources. Information obtained is used to support all categories of FBI investigations, from terrorism to violent crimes, and from health care fraud to organized crime.³

³ *Hearing on the 2000 Budget* before the Senate Committee on Appropriations, Subcommittee for the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies, at 280 (Prepared Statement of Louis Freeh, Director, FBI) (Mar. 24th, 1999), available online, www.gpo.gov (visited April 23, 2009). See also The Privacy Office, Department of Homeland Security, Privacy and Technology Workshop, Official Transcript at 19 (Sep. 8, 2005) ("[I]f you look back 23 years ago, if I wanted to gather information about a subject, We would have to physically go down to the courthouse to get real estate records, we would have to be sending these to another state to go get a driver's license record or a picture, we would have to go to a lot of different places, and manually gather this information So, I looked at commercial databases as a way to efficiently gather information....

II. The Publication of Information Does Not Become Commercial Speech Because the Information Is Used For Advertising or Other Commercial Purposes.

Not only is the activity of organizing, compiling and selling lawfully obtained, truthful information constitutionally protected speech, rather than conduct, that speech does not become less-protected "commercial speech" because those who obtain the information might use it for advertising or other commercial purposes. Newspapers, books and periodicals do not lose their fully protected First Amendment status because purchasers and subscribers use information contained in them for advertising or other commercial purposes. No basis exists for reaching a different conclusion with respect to digital informational databases.

Rationales that permit greater government regulation of commercial advertising have no application to the creation and publication of informational databases that have none of the characteristics associated with commercial speech. Activities like *amici*'s and those of the plaintiffs in this case pose no "risk of fraud," *R.A.V. v. St. Paul*, 505 U.S. 377, 388 (1992) (cited in *Lorillard Tobacco Company v. Reilly*, 533 U.S. 525, 576 (2001))

(comments of Chris Swecker, Assist. Director of the Criminal Investigative Division for the FBI), *available online*, http://www.dhs.gov/xlibrary/assets/privacy/privacy_wks_hop_09-2005_transcript_panell1.pdf (last viewed Apr. 23, 2009).

(Thomas, J., concurring)), nor do they involve "misleading, deceptive, or aggressive sales practices," see *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501 (1996) (Stevens, Kennedy, & Ginsburg, J.J., concurring) that have in the past permitted more robust regulation of commercial speech. E.g., *Florida Bar v. Went For It*, 515 U.S. 618, 635 (1995) (upholding 30 day ban on lawyer direct-mail solicitation to accident victims). Cf. *Lowe v. SEC*, 472 U.S. 181, 210 (1985) (noting that the dangers of "fraud, deception and overreaching" are "not replicated in publications [such as newspapers] that are advertised on the open market"). Unless the information in a database is accurate, it is of no value to those who use it.⁴ A land title document, for

⁴ The sole instance in which the rationales supporting commercial speech regulation apply is when solicitation or advertising occurs as an integral part of the message that the speaker wishes to communicate. Thus, although the Court has adopted different tests to determine whether commercial speech is present (cf. Pet. at 21-23), the presence of advertising by the person regulated by the statute is the *sine qua non* that ties these cases together. See also, e.g., *Thompson v. Western States Medical Center*, 535 U.S. 357, 366 (2002) (parties conceding that advertising and solicitation constitute commercial speech); *Lorillard Tobacco*, 533 U.S. at 534-37 (tobacco advertising); *44 Liquormart*, 517 U.S. at 489 (ban on advertising liquor pricing); *Edenfield v. Fane*, 507 U.S. 761, 764 (1992) (face-to-face solicitation by certified public accountant); *Bd. Of Trs. Of the State Univ. of New York v. Fox*, 492 U.S. 469, 472-74 (1989); *Bolger v. Youngs Drugs Prod. Corp.*, 463 U.S. 60, 62 (1983); *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 559 (1980) (ban on advertising during energy shortage); *Bates v. State Bar of Ariz.*, 433 U.S. 350, 355 (1977) (attorney advertising); *Virginia Pharmacy*, 425 U.S. at 750-51 (ban on drug prices in advertisements). These cases do not support application of the commercial speech doctrine to

example, is useless to a prospective land buyer if it contains erroneous information in the same way that an inaccurate list of commodity prices is useless to a futures trader. There is absolutely no incentive for *amici* or any other database producer to falsify the contents of their databases because to do so would destroy the economic viability of the database.

III. The First Circuit's Incorrect Decision Threatens *Amici's* Materials With a Host of New, Debilitating Regulation That Would Interfere Seriously with the Accuracy and Completeness of Informational Databases.

It is impossible to predict with certainty the particular legislative destructive enactments likely to be encouraged by the First Circuit's incorrect First Amendment analysis. The potential to do real harm to First Amendment values, however, is real. The conclusion that the collection and publication of truthful, lawfully obtained information is conduct, not speech, and thus entitled to no protection under the First Amendment, would give state and local legislatures unprecedented leeway to enact legislation inhibiting the free flow of that information. And even if the First Circuit's speech/conduct reasoning were rejected, its improper application of the commercial speech doctrine could result in denying necessary First Amendment protections.

cases in which the speaker is not *directly* engaging in advertising of any kind.

The First Circuit's conclusion that the gathering and publication of lawfully acquired, truthful information is "conduct" rather than speech, would subject laws governing these activities to the lowest level of judicial scrutiny, under which laws must be upheld if there is "any conceivable set of facts that could provide a rational basis" for their enactment. See *FCC v. Beach Communications*, 508 U.S. 307, 313-14, 315 (1993). At this level of scrutiny, the existence of any plausible policy justification will validate a statute with no requirement that a court either balance the strength of the asserted justification against the value to the public of the information that is suppressed, or consider whether the regulation excessively constrains expressive activity. This highly deferential standard of judicial review enables the government to enact regulations that would directly affect both *amici's* activities and the welfare of the customers that they serve. The First Circuit's alternative "commercial speech" holding would afford informational databases somewhat greater, but nonetheless inadequate, protection.

In the present case, New Hampshire has interfered with the availability of useful information, valuable for many non-"detailing" purposes, because of its attempt to regulate detailing. Instead of addressing its concerns directly, the state has cut off the free flow of useful information. Other legislatures could use the same technique to prohibit publication of data on embryonic stem cell research or abortion.

Amici have seen initiatives in various places that are harbingers of what may come if the First Circuit decision is upheld. One example of the kind

of regulation that would apparently be permitted if informational databases were to receive less than full First Amendment protection might be designed to produce state or local government revenue. State legislatures might be tempted to follow the lead of California's Santa Clara County, which attempted to raise revenue by prohibiting commercial re-use of digital real estate tax maps by requiring any commercial provider to pay substantial license fees far greater than the cost to the state of making these records available and prohibiting parties that acquire information from the government from making that information available to others. See Bruce Joffe, Case File: Santa Clara County, Ensuring Public Access to Geospatial Data, *GEO World* (Sept. 1 2007) (describing litigation over the county's charging of license fees and prohibition against redistributing the data). *County of Santa Clara v. Superior Court (California 1st Amendment Coalition)*, No. H031658, 2009, Cal. App. LEXIS 274 (Cal. App. 6th Dist. Feb. 27, 2009). This ill-advised policy might have resulted in revenue for the state, but would have resulted in incomplete databases of California public records. Compare also *Microdecisions v. Skinner*, 889 So. 2d 871, 872-73 (Fla. App. 2004) (rejecting attempt by property appraiser to demand royalty for commercial republication of public records under state law).

Last year, a special commission of the American Bar Association proposed a resolution that called upon state legislatures to enact laws that would bar *amicus* National Association of Background Screeners' members from disseminating

certain conviction records.⁵ The proposal was driven by concerns that criminal background checks may prevent ex-offenders from obtaining employment. Such concerns are legitimate, but preventing the distribution would almost certainly result in an inability to know whether convicted felons are being hired for appropriate occupations. The solution to this problem is not to dam the flow of information, but to use less speech-destructive tools such as tax incentives for employers who hire ex-offenders and/or to strengthen applicable anti-discrimination laws.

As individual jurisdictions carve out niches of information they wish to suppress, the result will be incomplete, fractured databases of little value and use. Suppose, for example, that a state wished to stop the rapid sales of homes in an area to prevent civic blight. To that end, the government would be tempted to make it illegal to collect and publish readily available real estate information for the purpose of engaging in real estate transactions because the government was aware that the information would subsequently be used to engage in home sales. Despite the fact that the information is lawfully acquired and disseminated, the collection and sale of that information under the First Circuit's speech/conduct line drawing or its interpretation of the First Amendment would receive reduced or no

⁵ See ABA Commission on Effective Criminal Sanctions, Limiting Access to Criminal History Information (August 2007), *available online*, www.abanet.org/dch/committee.cfm?com=CR209800 (visited 24 April December 2009). That proposal was withdrawn in part due to First Amendment concerns. See *id.* (press release from Reporter's Committee).

First Amendment protection because the purchasers of the information used it for purposes deemed "improper" by the government—irrespective of the fact that the state could have addressed its "blight" concerns through various other means such as new zoning requirements.

Under the First Circuit's analysis, regulations of this kind could be upheld regardless of the negative impact on information availability and flow, and despite the fact that there is a broad First Amendment right to receive such information and even though alternatives exist that do not do violence to the free speech rights of the publisher.

If a "marketplace of ideas" means anything, it must mean that the *users* of information, not the government, are to determine the value of truthful information in all but the most compelling cases. Consequently, the government must censor speech only as a last resort. By reducing or eliminating the First Amendment protection on the collection and publication of truthful, lawfully acquired information in the absence of any of the traditional indicia for such treatment, the First Circuit's decision has turned the First Amendment on its head.

Conclusion

For the foregoing reasons, the petition for a writ of certiorari should be GRANTED.

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IN THE
Supreme Court of the United States

IMS HEALTH, INC., ET AL.,
PETITIONERS

v.

KELLY A. AYOTTE, ATTORNEY GENERAL OF NEW
HAMPSHIRE,
RESPONDENT

On Petition for Writ of Certiorari to the United States
Court of Appeals for the First Circuit

**BRIEF OF *AMICUS CURIAE* ASSOCIATION OF
NATIONAL ADVERTISERS, INC. IN SUPPORT OF
PETITIONERS**

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CORPORATE DISCLOSURE STATEMENT

Although not strictly required by Rule 29.6 or 37.5, the instant *Amicus* submits the following corporate disclosure statement:

Amicus is incorporated as a nonprofit trade association, has no parent corporation, and has no stock or other interest owned by a publicly held company.

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BRIEF OF *AMICUS CURIAE* ASSOCIATION OF
NATIONAL ADVERTISERS, INC. IN SUPPORT
OF PETITIONERS

Amicus Curiae, the Association of National Advertisers, Inc. ("ANA"), respectfully requests that this Court grant the petition for writ of certiorari.¹

INTEREST OF *AMICUS CURIAE*

The ANA leads the marketing community by providing insights, collaboration and advocacy to its membership, which includes over 350 companies with 9,000 brands that collectively spend over \$100 billion in marketing communications and advertising annually in the United States. The ANA strives to communicate marketing best practices, to lead industry initiatives, to influence industry practices, to manage industry affairs, and to advance, promote and protect advertisers and marketers. The ANA also serves its members by advocating clear and coherent legal standards governing advertising, including this Court's commercial speech doctrine.

The decision in *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008) strikes at the heart of these interests. The First Circuit upheld New Hampshire's Prescription Information Law ("PIL"), which bans the communication or use of drug prescribing histories for commercial purposes.² To

¹ No counsel for a party authored this brief in whole or in part and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person, other than the *amicus curiae* or its counsel, made a monetary contribution to its preparation or submission. The parties have been given at least ten days notice of the intention of *amicus* ANA to file, and have consented to the filing of this brief.

² Specifically, the PIL provides that "[r]ecords relative to prescription information . . . shall not be licensed, transferred, used, or sold . . . for any commercial purpose," which it defines broadly to include "advertising, marketing, promotion, or any

reach this conclusion, the court below held that the transfer of truthful, nonmisleading data could be characterized as "conduct," not speech, and thereby avoid First Amendment scrutiny altogether. *Id.* at 50-54. Alternatively, the court analyzed the law under the commercial speech doctrine, *id.* at 54-60, and held that the statute's expansive definition of restricted activities, which extends far beyond speech proposing a commercial transaction, justified applying the lower level of constitutional protection set forth in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980).

Both conclusions undermine the constitutional protections guaranteed to ANA's members, contradict this Court's commercial speech jurisprudence, perpetuate confusion among the circuit courts, and require correction by this Court.

SUMMARY OF THE ARGUMENT

ANA supports all of the arguments for review raised in the Petition. Not only did the circuit court below fail to apply correctly long-settled principles under the commercial speech doctrine,³ the opinion

activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force." N.H. Rev. Stat. Ann. § 318:47-f.

³ For example, the First Circuit found that it "demand[s] too much" to require New Hampshire to document that the ban on data mining would serve its asserted interest because "New Hampshire was the first state to deny detailers access to prescribing histories." *IMS Health Inc.*, 550 F.3d at 58. Such deference to "legislative judgment" where "evidence simply does not exist," *id.*, flies in the face of numerous decisions of this Court holding that "a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Edenfield v. Fane*, 507 U.S. 761, 771 (1993); *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 373 (2002); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 486-87 (1995). See 44 *Liquormart, Inc. v. Rhode*

further obscures important issues that have not yet been fully resolved by this Court. Notwithstanding our endorsement of the points raised in the Petition, this brief focuses principally on two issues: (1) whether the exchange of factual information can be denied First Amendment protection simply by characterizing it as "conduct," and (2) whether the standard for commercial speech articulated in *Central Hudson* applies more broadly beyond speech that does no more than propose a commercial transaction. Regardless whether the test for commercial or noncommercial speech is applied, the court below erred in upholding the New Hampshire law.

The First Circuit's conclusion that the PIL is immune from First Amendment scrutiny because it prohibits only "conduct" is unsupported by the decisions of this Court and greatly confuses First Amendment jurisprudence. To be sure, categories of unprotected speech exist, but not because they are considered to be conduct rather than expression. Contrary to the reasoning of the court below, this Court's decisions have long extended First Amendment protection to the entire communication process, from the gathering and printing of information through its dissemination. Such protection is unaffected by the fact that communication requires some form of "conduct" or the information may be labeled a "commodity."

The lower court's conclusion that constitutional protection may be withheld to parts of a communicative enterprise that may be characterized as "conduct" is profoundly dangerous for First

Island, 517 U.S. 484, 508-11 (1996) (rejecting "legislative judgment" that a ban on alcohol price advertising would promote temperance). Nothing in this Court's cases supports the conclusion that New Hampshire's burden of proof disappears or is lessened simply because it is the first state to adopt such restrictions.

Amendment law in general, and not just with respect to commercial speech. All expression requires conduct of some kind, and there is no logical limit to the restrictions that may be imposed if the government can freely restrict components of expression it deems to be "conduct." This Court has long rejected the notion that the state is free from constitutional constraints by claiming only to regulate the process of communication or by calling it business activity. The decision below is at odds with this clear line of authority and conflicts with decisions in other circuits that have recognized protection for the collection and use of commercial data.

The First Circuit decision also highlights an unsettled question about the scope of the commercial speech doctrine. This Court has long grappled with whether to define commercial expression broadly, as speech related to the commercial interests of the speaker, or more narrowly, as speech that does no more than propose a commercial transaction. The question is of vital importance, because the answer determines whether expression is accorded the somewhat less rigorous constitutional protections that historically have been applied to commercial speech.

In this case, the First Circuit's embrace of the broader definition based on the speaker's commercial interests conflicts with the clear trend of this Court's decisions that have applied an increasing level of protection for commercial speech. In doing so, it exploited the fact that this Court has not explicitly resolved the definitional question, even though the prevailing logic of the cases supports the narrower formulation. The decision below deepened a split among the circuit courts on this question and threatens to obscure the scope of the commercial speech doctrine. Review by this Court is essential.

ARGUMENT

I. THE DECISION BELOW BREAKS SHARPLY WITH THE GENERAL TREND RECOGNIZING GREATER PROTECTION FOR COMMERCIAL SPEECH

For more than three decades, this Court has recognized that "a particular consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 763 (1976). See also *Bigelow v. Virginia*, 421 U.S. 809, 818-20 (1975). In addition to the needs of particular individuals, "society also may have a strong interest in the free flow of commercial information," and a particular advertisement, "though entirely 'commercial,' may be of general public interest." *Virginia State Bd. of Pharmacy*, 425 U.S. at 764. These observations – and the legal doctrine that emerged from them – did not limit First Amendment protection only to advertising that related in some way to a "public" issue. This Court explained that the constitutional interest in commercial speech is the "dissemination of information as to who is producing and selling what product, for what reason, and at what price" in order to facilitate "numerous private economic decisions." *Id.* at 765. "To this end, the free flow of commercial information is indispensable." *Id.*

Spawning the development of the commercial speech doctrine, *Virginia State Board of Pharmacy* represented a sharp break with the Court's prior approach to such expression. For example, nascent First Amendment jurisprudence denied constitutional protection to cinema and allowed states to ban films, reasoning that "[t]he exhibition of moving pictures is a business, pure and simple, originated and conducted for profit." *Mutual Film Corp. v. Industrial Comm'n*, 236 U.S. 230, 244

(1915). Among other things, the Court observed that, while opinion is free, "conduct alone is amenable to the law." *Id.* at 243 (emphasis added). It likewise upheld a state law that banned the use of images of the American flag "as an advertisement on a bottle of beer." *Halter v. Nebraska*, 205 U.S. 34, 42 (1907). Similarly, in *Valentine v. Chrestensen*, 316 U.S. 52, 53 (1942), the Court upheld a provision of the New York Sanitary Code that prohibited the act of "distribut[ing] in the streets . . . commercial and business advertising matter." *See id.* at 54 (prohibiting "such activity" is a matter of legislative judgment and does not violate the Constitution).

The "simplistic approach" of *Chrestensen* and prior commercial speech cases has been thoroughly repudiated by this Court,⁴ and a separate test was fashioned for "speech which does 'no more than propose a commercial transaction.'" *Virginia State Bd. of Pharmacy*, 425 U.S. at 762 (quoting *Pittsburgh Press Co. v. Human Relations Comm'n*, 413 U.S. 376, 385 (1973)). In *Central Hudson*, 447 U.S. at 562-63, 566, this Court established a four part inquiry for determining the constitutionality of restrictions on commercial speech, but also held that the Constitution accords somewhat less (but still substantial) protection in this area than it does for non-commercial expression.

Decisions issued since then have increased significantly the level of protection for commercial speech, and in the past two decades the Court has

⁴ *Virginia State Bd. of Pharmacy*, 425 U.S. at 759 ("the notion of unprotected 'commercial speech' [has] all but passed from the scene"). *See Bigelow*, 421 U.S. at 818-20. For a precursor to these decisions, see *Joseph Burstyn, Inc. v. Wilson*, 343 U.S. 495, 501-02 (1952) ("That books, newspapers, and magazines are published and sold for profit does not prevent them from being a form of expression whose liberty is safeguarded by the First Amendment. We fail to see why operation for profit should have any different effect in the case of motion pictures.").

invalidated: (1) an ordinance that regulated the placement of commercial newsracks, *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 430-31 (1993); (2) a state ban on in-person solicitation by CPAs, *Edenfield*, 507 U.S. at 777; (3) a state ban on using the designations "CPA" and "CFP" on law firm stationery, *Ibanez v. Florida Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136 (1994); (4) a restriction on listing alcohol content on beer labels, *Rubin*, 514 U.S. at 491; (5) a state ban on advertising alcohol prices, *44 Liquormart*, 517 U.S. at 516; (6) a federal ban on broadcasting casino advertising, *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173 (1999); (7) state regulation of tobacco advertising, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001); and (8) FDA restrictions on advertising the practice of drug compounding, *Western States Med. Ctr.*, 535 U.S. at 377.

Even as this Court has approved an increasing level of protection for purely commercial messages, it has stressed the importance of clarifying the distinction between fully protected expression and that which falls under the commercial speech doctrine. The *Central Hudson* Court cautioned that "special care" should be taken in the case of any ban on speech, noting that "in recent years, this Court has not approved a blanket ban on commercial speech unless the expression itself was flawed in some way, either because it was deceptive or related to unlawful activity." *Central Hudson*, 447 U.S. at 566 n.9. Clarity in drawing this line is essential "to ensure that speech deserving of greater constitutional protection is not inadvertently suppressed." *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66 (1983); *Discovery Network*, 507 U.S. at 422-23. See also *id.* at 423 n.19 ("[T]he responsibility for distinguishing between the two carries with it the potential for invidious discrimination of disfavored subjects.").

The search for predictable standards has prompted continuing debate on the Court about the breadth of the commercial speech doctrine and even the propriety of maintaining a separate constitutional standard at all. *See, e.g., 44 Liquormart*, 517 U.S. at 501 (Stevens, J., plurality op.) ("The mere fact that messages propose commercial transactions does not in and of itself dictate the constitutional analysis that should apply to decisions to suppress them."); *id.* at 523-24 (Thomas, J., concurring) ("I do not believe that such a test should be applied to a restriction of 'commercial' speech, at least when, as here, the asserted interest is one that is to be achieved through keeping would-be recipients of the speech in the dark."); *id.* at 517 (Scalia, J., concurring in part) ("I share Justice Thomas's discomfort with the *Central Hudson* test, which seems to me to have nothing more than policy intuition to support it."). *See also Rubin*, 514 U.S. at 493 (Stevens, J., concurring) ("The Court's continued reliance on the misguided approach adopted in *Central Hudson* makes this case appear more difficult than it is."); *Discovery Network*, 507 U.S. at 438 (Blackmun, J., concurring) ("I hope the Court ultimately will come to abandon *Central Hudson's* analysis entirely in favor of one that affords full protection for truthful, noncoercive commercial speech about lawful activities."). In short, this Court's commercial speech jurisprudence has never fully resolved some fundamental issues regarding the scope of the doctrine and its application to particular situations.

The decision below does not raise a challenge to the continuing validity of *Central Hudson*, but it presents fundamental questions about the government's ability to avoid First Amendment scrutiny altogether when it bans the exchange of truthful information, as well as the proper definition of commercial speech. It constitutes a sharp break with the general trend of commercial speech cases

that have recognized greater protection for the free flow of commercial information, and it adds to confusion among the circuit courts.

II. THE CIRCUIT COURT DECISION CONTAINS FUNDAMENTAL DOCTRINAL ERRORS THAT REQUIRE CORRECTION AND CLARIFICATION BY THIS COURT

A. The First Circuit's Finding That The New Hampshire Law Regulates Only Conduct Is Patently Erroneous

The central premise of the circuit court decision is that the dissemination of prescribing histories for commercial purposes may be banned without any First Amendment scrutiny *at all* so long as the information is characterized as a "commodity." *IMS Health Inc.*, 550 F.3d at 53. Describing the PIL as a regulation of "conduct, not expression," the court's analysis is summed up thusly:

The plaintiffs, who are in the business of harvesting, refining, and selling this commodity, ask us in essence to rule that because their product is information instead of, say beef jerky, any regulation constitutes a restriction of speech. We think that such an interpretation stretches the fabric of the First Amendment beyond any rational measure.

Id. This bizarre analogy is wrong, if for no other reason because the State of New Hampshire is *not* regulating beef jerky – it is banning the flow of information *because* it may be used to persuade. Calling the information used to engage in protected speech a "commodity" does not make it chopped liver, or, to parrot the lower court's strained metaphor, dried beef.⁵ Nor is there any support in

⁵ Judge Lipez dissented in part, correctly reasoning that the court may not "insulate this expression-based intention [of

this Court's opinions for such constitutional sleight of hand. *See, e.g., Smith v. California*, 361 U.S. 147, 152 (1959) (rejecting an analogy between regulating speech and regulating food); *NAACP v. Button*, 371 U.S. 415, 429 (1963) ("[A] State cannot foreclose the exercise of constitutional rights by mere labels.").

Judge Selya's majority opinion begins with the unexceptional observation that "it has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *IMS Health Inc.*, 550 F.3d at 51 (quoting *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 62 (2006) (citation omitted)). From this basic premise, he leaps to the indefensible conclusion that the "course of conduct" that may be banned without constitutional implications is the gathering and use of truthful, nonmisleading information for purposes of "advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product," and other related communications.

It is no doubt true that the use of language or information is not an absolute litmus test for First Amendment protection. Certain types of expression, such as extortion, perjury, bomb threats, price fixing agreements, or publication of state secrets, traditionally have been held to be unprotected, notwithstanding the fact that they necessarily involve the use of "speech." *See, e.g.,* Frederick F. Schauer, *The Aim and Target in Free Speech Methodology*, 83 NW. U. L. REV. 562, 563 (1989). The First Circuit majority purports to identify "a doctrinal mystery" by citing examples of other laws

the PIL] from First Amendment scrutiny by directing its legislation to an earlier step in the communicative process." *IMS Health Inc.*, 550 F.3d at 80 (Lipez, J., concurring and dissenting).

that may be enforced without violating the First Amendment notwithstanding the "speech" component of the offense (e.g., antitrust laws, prohibitions against creating a hostile work environment, laws governing union elections), and concludes, based on its "felt sense" of the matter, that the information banned by the PIL falls within the same "complex of de facto exceptions" to constitutional protection. *IMS Health Inc.*, 550 F.3d at 52 (collecting cases). But none of those examples support the result below – that the communication of data may be suppressed simply because it may be used to persuade people to make what the government believes are "unwise" choices.⁶

In sleuthing out what it claims to be a mystery, the First Circuit instead simply misstates the question. The issue in the cases it cites is not that there is a tangible distinction between "speech" and "conduct;" it is whether the expression at issue may itself be considered a crime. The lower court's error is evident from its reference to obscenity, fighting words, and false commercial speech as the "proof of this pudding [] that entire categories of speech receive no protection at all from the First Amendment." *Id.* at 51-52. The existence of certain types of unprotected speech may be undeniable, but such categories are not identified by "conduct." See *R.A.V. v. City of St. Paul*, 505 U.S. 377, 383-84 (1992) ("[T]hese areas of speech can, consistently

⁶ See 44 *Liquormart*, 517 U.S. at 503 ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good."). The court below seeks to bolster its conclusion by asserting that the speech banned by the PIL "is of scant societal value," *IMS Health Inc.*, 550 F.3d at 52, but such an imperious observation ignores the teaching of this Court that "the speaker and the audience, not the government, assess the value of the information presented." *Western States Med. Ctr.*, 535 U.S. at 367 (quoting *Edenfield*, 507 U.S. at 767).

with the First Amendment, be regulated *because of their constitutionally proscribable content* (obscenity, defamation, etc.), not that they are categories of speech entirely invisible to the Constitution, so that they may be made the vehicles for content discrimination unrelated to their distinctively proscribable content.") (emphasis in original). No precedent supports making the gathering and communication of truthful information for commercial purposes a criminal act.

What *does* create a doctrinal mystery is finding a stopping point if other courts were to accept the First Circuit's proposition that regulating or banning a component of speech as "conduct" requires no First Amendment scrutiny. *IMS Health Inc.*, 550 F.3d at 51-52. This is because all expression requires conduct. The printing and circulation of newspapers entails a great deal of physical activity, and, as more than one commentator has noted, the same can be said of speech "even if it only be the use of one's vocal chords." Melville B. Nimmer, *FREEDOM OF SPEECH* § 3.06[B] n.15 (1984); Laurence H. Tribe, *AMERICAN CONSTITUTIONAL LAW* 827 (2d ed. 1988) ("[A]ny particular course of conduct may be hung almost randomly on the 'speech' peg or the 'conduct' peg as one sees fit."); Harry Kalven, Jr., *The Concept of the Public Forum: Cox v. Louisiana*, 1965 SUP. CT. REV. 1, 23 ("[A]ll speech is necessarily 'speech plus.']"). The Ninth Circuit has observed that "speech in any language consists of the 'expressive conduct' of vibrating one's vocal chords, moving one's mouth and thereby making sounds, or of putting pen to paper, or hand to keyboard." *Yniguez v. Arizonans for Official English*, 69 F.3d 920, 934 (9th Cir. 1995) (*en banc*), *vacated as moot*, 520 U.S. 43 (1997). Consequently, if the First Circuit were correct that the government could freely regulate any "conduct" required for expression, then the only communication that would be fully protected under the First Amendment would be telepathy. *See* Tribe,

supra at 827 (“[A]ll communication except perhaps the extrasensory variety involves conduct.”).

The First Circuit’s erroneous analysis is not limited to commercial speech. As its citation of cases on other subjects suggests, its reasoning would permit the government to ban any discrete component of the communications process, so long as that activity could be characterized as “conduct.” However, as this Court has made quite clear in numerous cases, the government runs afoul of the Constitution when it attempts to single out and restrict any particular part of a communicative enterprise under the rubric of regulating action and not speech.

Thus, the First Amendment has been held to protect the materials necessary for printing, *Minneapolis Star & Trib. Co. v. Minnesota Comm’r of Revenue*, 460 U.S. 575 (1983) (striking down tax on newsprint and ink); newsgathering activities, *Richmond Newspapers, Inc. v. Virginia*, 448 U.S. 555 (1980) (First Amendment requires right of access to criminal trials); and circulation of publications, including the physical placement of newsboxes. *City of Lakewood v. Plain Dealer Publ’g Co.*, 486 U.S. 750 (1988). See *Lovell v. City of Griffin*, 303 U.S. 444, 452 (1938) (“Liberty of circulating is as essential to th[e] freedom [of the press] as liberty of publishing; indeed, without the circulation, the publication would be of little value.”) (citation omitted). It has also held that the First Amendment protects campaign expenditures and contributions, since restricting such actions necessarily reduces the quantity of expression in political campaigns by restricting the number of issues discussed, the depth of their exploration, and the size of the audience reached. *Randall v. Sorrell*, 548 U.S. 230, 246 (2006). Such precedents foreclose the First Circuit’s conclusion.

This clear line of authority is unaffected by the fact that the communication New Hampshire has banned has a commercial purpose, *i.e.*, that information is used as "a commodity." *IMS Health Inc.*, 550 F.3d at 53. As this Court pointed out in *Bigelow*, 421 U.S. at 818, "[o]ur cases . . . clearly establish that speech is not stripped of First Amendment protection merely because it appears in [commercial] form." It explained further that First Amendment protections for commercial speech extend to the entire communication process, which includes the communication, its source and its recipients. *Virginia State Bd. of Pharmacy*, 425 U.S. 756-57. *Cf. Grosjean v. American Press Co.*, 297 U.S. 233, 240, 244-45 (1936) (invalidating tax imposed on any person or corporation "engaged in the business of selling . . . advertising or for advertisements, whether printed or published"). To hold otherwise – as the First Circuit did below – threatens to return First Amendment jurisprudence to the era in which films could be banned because "[t]he exhibition of moving pictures is a business, pure and simple, originated and conducted for profit," *Mutual Film Corp.*, 236 U.S. at 244, and commercial handbills could be outlawed because "distribut[ing] . . . commercial and business advertising matter" could result in litter. *Chastensen*, 316 U.S. at 53-54.

The majority opinion below attempts to minimize the drastic implications of its logic by claiming that "detailing," using drug prescription data, is just part of the "art of marketing" that is used "[i]n the service of maximizing drug sales [whereby] detailers use prescribing histories as a means of targeting potential customers more precisely and as a tool for tipping the balance of bargaining power in their favor." *IMS Health Inc.*, 550 F.3d at 54. However, the lower court's flurry of words distinguishing "targeted marketing" from protected speech lacks any logical or legal support. The value of advertising

depends on the ability to get the message to the right audience, and this Court has held that a restriction on targeted marketing efforts necessarily implicates the First Amendment. *E.g., Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995). As the Tenth Circuit noted in striking down a ban on the use of customer data to make targeted solicitations, "a restriction on speech tailored to a particular audience, 'targeted speech,' cannot be cured simply by the fact that a speaker can speak to a larger indiscriminate audience, 'broadcast speech.'" *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232 (10th Cir. 1999).

At the very least, review by this Court is essential to correct the doctrinal confusion engendered by the First Circuit's decision and to clarify a division among the circuit courts about the First Amendment protection accorded such commercial data. Contrary to the lower court's finding that the compilation and communication of information on prescribing histories may be regulated as conduct because the "putative speech comprises items of nugatory informational value," *IMS Health Inc.*, 550 F.3d at 52, at least two other circuits have held that the distribution of purely factual information for a commercial purpose is constitutionally protected. As noted above, the Tenth Circuit in *U.S. West, Inc.*, 182 F.3d at 1232, held that prohibiting the use of customer proprietary network information ("CPNI") to make targeted sales presentations violates the First Amendment. *See also Lanphere & Urbaniak v. Colorado*, 21 F.3d 1508, 1513 (10th Cir. 1994). The D.C. Circuit has reached the same conclusion. *NCTA v. FCC*, 555 F.3d 996, 1000 (D.C. Cir. 2009). Under circumstances analogous to the facts of this case, these circuits have applied the widely understood principle that "[e]ven dry information, devoid of advocacy, political relevance, or artistic expression," merits First Amendment protection. *E.g., Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446-47 (2d

Cir. 2001). The anomalous decision in this case thus has split the circuits and requires review.

B. The First Circuit's Definition Of Commercial Speech Is Excessively Broad

This Court has struggled for years to devise a uniform definition of commercial speech, recognizing that crafting a coherent definition is a critical threshold question that determines the level of First Amendment protection that will apply in a given case. It has described "*the test* for identifying commercial speech," as speech that does no more than propose a commercial transaction, *Discovery Network*, 507 U.S. at 423 (quoting *Board of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473-74 (1989)) (emphasis in original), but has also referred more generally to "expression related solely to the economic interests of the speaker and its audience." *Central Hudson*, 447 U.S. at 561. This case underscores the pressing need for the Court to clarify the proper application of the commercial speech doctrine.

Without a definitive word from this Court as to whether the broader or narrower formulation should control, the circuits have become deeply divided, and the decision below only makes matters worse. In addition to the First Circuit below, three circuits have adopted the broader definition, which subjects more speech to a lesser degree of First Amendment protection. See *SKF USA, Inc. v. U.S. Customs and Border Prot.*, 556 F.3d 1337, 1355 (Fed. Cir. 2009); *Mason v. Florida Bar*, 208 F.3d 952, 955 (11th Cir. 2000); *Hoover v. Morales*, 164 F.3d 221, 225 (5th Cir. 1998). The opinion below "reject[ed]" the narrower test set forth in *Fox* and *Discovery Network* in favor of the more encompassing definition applied in other First Circuit cases. *IMS Health Inc.*, 550 F.3d at 54-55. See, e.g., *Pharmaceutical Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 309 (1st Cir. 2005). The analysis of the court below was then picked up by a

divided Federal Circuit in *SKF USA, Inc.*, 556 F.3d at 1355. *But see id.* at 1371 n.5 (Linn, J., dissenting) (narrower definition should apply and "*IMS* was incorrectly decided"). At the same time, three other circuits apply the narrower definition set forth by this Court as speech that does no more than propose a commercial transaction. *Mattel, Inc. v. MCA Records, Inc.*, 296 F.3d 894, 906 (9th Cir. 2002); *CFTC v. Vartuli*, 228 F.3d 94, 110 n.8 (2d Cir. 2000); *Adventure Commc'ns, Inc. v. Kentucky Registry of Election Fin.*, 191 F.3d 429, 440 (4th Cir. 1999).

In this case, the decision below is erroneous regardless whether *Central Hudson* or the test governing restrictions on noncommercial speech applies. *See supra* nn.3, 6. But the breadth of speech covered by the PIL highlights the importance of defining commercial speech precisely. The law prohibits the collection or use of prescriber data for "any commercial purpose," which goes far beyond advertising or proposing a commercial transaction to include "any activity that could be used to influence sales or market share of a pharmaceutical product," any evaluation of "the prescribing behavior of an individual health care professional," or any assessment of "the effectiveness of a professional pharmaceutical detailing sales force." N.H. Rev. Stat. Ann. § 318:47-f. In this connection, the Petition notes the array of non-marketing uses of such data, including "track[ing] patterns of disease and treatment, conduct[ing] research and clinical trials, implement[ing] best practices, and engag[ing] in economic analyses." Pet. at 17. Given the state's expansive conception of commercial speech and the lower court's analysis, the Court should grant review to ensure that fully-protected speech is not "inadvertently suppressed." *Bolger*, 463 U.S. at 66.

Finally, clarification by this Court of the definition of commercial speech is long overdue. Granting review on this issue would address a key question left open in *Nike, Inc. v. Kasky*, 539 U.S.

654 (2003) (*per curiam*). The California Supreme Court had applied the broader definition based on the speaker's commercial interest, and rejected Nike's argument that full First Amendment protection should have been applied because the speech at issue directly addressed a matter of public controversy. *Kasky v. Nike, Inc.*, 27 Cal. 4th 939, 946, 964-68, 119 Cal. Rptr. 2d 296, 45 P.3d 243 (2002). This Court initially granted review to consider the proper definition of commercial speech under *Central Hudson*, but after briefing and argument, dismissed certiorari as improvidently granted.⁷ Nevertheless, no one has ever disputed the importance of the issue that was left unresolved. Over thirty amicus briefs were filed in the case, and a majority agreed that the breadth of the commercial speech definition and the proper scope of *Central Hudson* were important doctrinal issues that warranted the Court's review in a proper case.⁸

The proper case has now arrived. There is no question but that the decision below, after a full trial on the merits, is final. Unfortunately, the ongoing dispute about the definition of commercial speech, coupled with the missed opportunity in *Nike* to

⁷ In an opinion concurring in the dismissal, Justice Stevens, joined by Justices Ginsburg and Souter, wrote that the decision below lacked finality because the California Supreme Court never entered a final judgment as required under 28 U.S.C. § 1257, and that the parties lacked standing to proceed in federal court. *Nike, Inc. v. Kasky*, 539 U.S. at 657-63 (Stevens, J., concurring).

⁸ Justice Stevens wrote that, under the doctrine of constitutional avoidance, the Court should not decide the matter prematurely *because of* "the novelty and importance of the constitutional questions." *Nike, Inc. v. Kasky*, 539 U.S. at 657-63 (Stevens, J., concurring) (Justice Souter did not join this part of the opinion). Justice Kennedy dissented from the dismissal without opinion. *Id.* at 665. Justice Breyer, joined by Justice O'Connor, also dissented, and wrote that he "would apply a form of heightened scrutiny to the speech regulations in question." *Id.* at 676 (Breyer, J., dissenting).

resolve the issue, permitted the First Circuit to add to the confusion among the circuits. As Justice Blackmun wrote in another context, "*Central Hudson's* chickens have come home to roost." *Discovery Network*, 507 U.S. at 436 (Blackmun, J., concurring). The Court should use this occasion to clarify this important area of the law.

CONCLUSION

For the foregoing reasons, *amicus* ANA respectfully requests that the Court grant the petition for certiorari.

Respectfully submitted,

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In The
Supreme Court of the United States

IMS HEALTH, INC. AND VERISPAN LLC,

Petitioners,

vs.

KELLY M. AYOTTE, AS ATTORNEY GENERAL
OF THE STATE OF NEW HAMPSHIRE,

Respondent.

On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The First Circuit

BRIEF OF *AMICI CURIAE* THE CENTER FOR
DEMOCRACY AND TECHNOLOGY, THE GENETIC
ALLIANCE, THE PHARMACEUTICAL CARE
MANAGEMENT ASSOCIATION, MARK FRISSE,
AND SARA ROSENBAUM
IN SUPPORT OF PETITIONERS

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**BRIEF OF THE CENTER FOR DEMOCRACY
AND TECHNOLOGY, THE GENETIC
ALLIANCE, THE PHARMACEUTICAL
CARE MANAGEMENT ASSOCIATION,
MARK FRISSE, AND SARA ROSENBAUM
AS *AMICI CURIAE* IN
SUPPORT OF PETITIONERS**

With the joint written consent of the parties, the Center for Democracy and Technology, The Genetic Alliance, The Pharmaceutical Care Management Association, Mark Frisse, and Sara Rosenbaum respectfully submit this brief as *amici curiae*.¹

INTERESTS OF *AMICI CURIAE*

The Center for Democracy and Technology ("CDT") is a non-profit Internet and technology advocacy organization which promotes public policies that preserve privacy and enhance civil liberties in the digital age. As information technology is increasingly used to support the exchange of medical records and other health information, CDT, through its Health Privacy Project, champions comprehensive

¹ *Amici curiae* and their counsel authored this brief in whole and no person or entity other than *amici* or its counsel has made a monetary contribution to the preparation or submission of this brief.

The parties were notified ten days prior to the due date of this brief of the intention to file. The parties have consented to the filing of this brief.

privacy and security policies to protect health data. CDT promotes its positions through public policy advocacy, public education, and litigation, as well as through the development of industry best practices and technology standards. CDT plays an instrumental role in safeguarding consumer privacy on the Internet. Recognizing that a networked health care system can lead to improved health care quality, reduced costs, and empowered consumers, CDT is using its experience to shape workable privacy solutions for a health care system characterized by electronic health information exchange.

Genetic Alliance transforms health through genetics, promoting an environment of openness centered on the health of individuals, families, and communities. Genetic Alliance brings together diverse stakeholders that create novel partnerships in advocacy; integrates individual, family, and community perspectives to improve health systems; and revolutionizes access to information to enable translation of research into services and individualized decision making.

The Pharmaceutical Care Management Association² ("PCMA") is the national association

² PCMA's members include the following: Aetna Inc.; Caremark Inc., a wholly-owned subsidiary of CVS/Caremark Corporation; CIGNA Health Corporation; Prime Therapeutics LLC; Express Scripts, Inc.; MC-21 Corporation; Medco Health Solutions, Inc.; RxSolutions, Inc. d/b/a Prescription Solutions, a wholly-owned subsidiary of PacifiCare Health Systems, LLC,

(Continued on following page)

representing pharmacy benefit managers (PBMs), which administer prescription drug benefits for more than 210 million Americans with health care coverage. PBMs work to drive down the cost of prescription drugs through proven cost-containment tools, including negotiating with drug manufacturers to obtain rebates on plan members' drug purchases; establishing networks of both retail and mail-order pharmacies to allow consumers access to discount drugs; and administering "drug utilization review" programs designed to monitor and deter purchases of dangerous drug combinations and questionable doses. PBMs also have been at the forefront in advancing cutting-edge technologies such as electronic prescribing, which provides physicians with clinical and cost information on prescription options that allows them to better counsel consumers regarding which medications are the safest and most affordable choices.

Mark Frisse is a physician and Accenture Professor of Biomedical Informatics at Vanderbilt University. Working on a five-year project funded by AHRQ and the State of Tennessee, Dr. Frisse was a

which in turn is a wholly-owned subsidiary of UnitedHealth Group Incorporated; Wellpoint Pharmacy Management (a d/b/a for Professional Claims Services, Inc.) and Anthem Prescription Management, LLC, both of which are wholly-owned subsidiaries of Wellpoint, Inc.; US Scripts, Inc.; and Scriptrax, part of Novant Health – a not-for-profit health care system.

leader in efforts to create a regional health information exchange involving all major providers in the Memphis area. The exchange has comprehensive data sharing agreements and supports care for over 750,000 people; it has been in operation for over two years. In addition, Dr. Frisse was involved in a large-scale data integration project in the mid-1990s that provided drug interaction alerts to pharmacists at the BJC Health System in St. Louis. He has also led workshops and authored comprehensive reports on privacy, confidentiality, and health information exchange.

Sara Rosenbaum is the Harold and Jane Hirsh Professor of Health Law and Policy and chair of the Department of Health Policy at the George Washington University School of Public Health Services. A leader in health policy, with a particular focus on health care access for medically underserved populations, Professor Rosenbaum is known nationally for her work on health insurance, national health reform, and health care access. For five years Professor Rosenbaum has led a series of studies for the United States Department of Health and Human Services that examine health information technology adoption among physicians and hospitals. She has written extensively on numerous aspects of health law, including health information law, and is a co-author of *Law and the American Health Care System* (Foundation Press).

The New Hampshire law at issue in this case is directly at odds with the policy objectives of *amici*. In

the service of privacy interests that do not exist, the law will impede efforts to reform our health care system and improve the quality and efficiency of health care provided to patients and populations. Therefore, *amici* write to assist the Court in analyzing the legal and public policy issues that warrant this Court's review of the decision of the Circuit Court of Appeals for the First Circuit.

SUMMARY OF ARGUMENT

1. The Court should grant the petition because the Prescription Information Law does not implicate any legitimate privacy interest. The New Hampshire Legislature and New Hampshire Attorney General have sought to justify the Prescription Information Law on the grounds that New Hampshire has an interest in protecting the privacy of both patients and prescribers, and that this interest requires limiting the exchange of prescription information. The Prescription Information Law, however, does not protect any legitimate privacy interest. Physicians have no privacy interest in their prescribing practices. Such practices are consistently revealed to, and reviewed by, numerous third-parties. Nor is patient privacy at issue here. The Prescription Information Law regulates "de-identified" patient information that does not implicate patient privacy. Further, tremendous public health benefits are associated with the transfer and use of de-identified health care information. Review by this Court is

therefore critical to facilitate the national interest in the use of health care information where, as here, it does not implicate any legitimate privacy interest.

2. The Court should grant the petition because the Prescription Information Law and copycat legislation in other states threaten to strangle efforts to use health care information technology to improve patient care and public health. Information technology has made it easier than ever to collect, exchange, aggregate, analyze, and communicate health information electronically. This has enormous potential benefits, including improved health outcomes, better quality of care, and lower costs. Indeed, President Obama recognized this potential when his administration authorized \$36 billion in federal stimulus funds to encourage adoption of health IT tools. But the New Hampshire Prescription Information Law – with its broad undefined prohibitions, and amorphous exceptions – threatens to undermine this important national trend.

ARGUMENT

I.

**THIS COURT SHOULD GRANT THE
PETITION FOR A WRIT OF CERTIORARI
BECAUSE PATIENTS AND HEALTH CARE
PROVIDERS DO NOT HAVE ANY PRIVACY
INTERESTS IN THE INFORMATION
THAT THE PRESCRIPTION
INFORMATION LAW PROTECTS**

The legislative record is replete with references to the supposed "privacy" interests that the Prescription Information Law would protect. Representative Cindy Rosenwald, one of the statute's co-sponsors, noted that the statute "will protect privacy . . . by prohibiting the sale or use of individual patient or prescriber identity."³ Further, in defending the statute below, the New Hampshire Attorney General justified the law on the grounds that it protects both patient and prescriber policy.

These "privacy" considerations are phantoms. The Prescription Information Law does not protect any legitimate privacy interest.

First, there is no physician privacy to protect because physicians have no expectation of privacy in

³ See An Act Requiring Certain Persons To Keep the Contents of Prescriptions Confidential: Hearing on H.B. 1346 Before the S. Comm. on Exec. Departments & Administration, 159th Sess. Gen. Ct. 1 (N.H. 2006) (statement of Rep. Cindy Rosenwald, Member, House of Representatives).

their prescribing practices. As the District Court noted below, the provisions challenged here relate to the professional practice of prescribers, not personal information. *IMS Health, Inc. v. Ayotte*, 490 F. Supp. 2d 163, 179 n.13 (D.N.H. 2007). Thus, health care providers, who work in a "closely regulated" industry, cannot claim *any* expectation of privacy over their professional practices because "prescriber-identifiable data is routinely disclosed to patients, pharmacies, insurance companies, medical review committees, and government agencies." *Id.* (citing *New York v. Burger*, 482 U.S. 691, 702, 107 S. Ct. 2636, 96 L. Ed. 2d 601 (1987)); *see also Marshall v. Barlow's, Inc.*, 436 U.S. 307, 313, 98 S. Ct. 1816, 56 L. Ed. 2d 305 (1978) ("Certain industries have such a history of government oversight that no reasonable expectation of privacy could exist . . .") (internal citation omitted).

Second, the Prescription Information Law does not implicate patient privacy. While it purports to protect privacy interests, the statute regulates patient *de-identified* information. At the federal level, the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d et seq. ("HIPAA"), provides rigorous standards for de-identifying information, which involve either certification by a statistician that the information has been de-identified or the removal of specific identifiers including name, social security number, medical record number, and address.

HIPAA also sets national standards for the use and disclosure of Americans' *identifiable* health

information. Specifically, the HIPAA Privacy Rule regulates the use and disclosure of Protected Health Information ("PHI"), i.e., information concerning health status, provision of health care, or payment for health care that identifies an individual. HIPAA recognizes the need to place clear, enforceable parameters around the use of such identifiable information. In contrast, HIPAA expressly does *not* restrict the use or disclosure of de-identified health information, which is sufficiently stripped of patient identifiers that its use and disclosure raises no privacy risk to patients.

In making this distinction, HIPAA highlights the substantial public health benefits of permitting broad access to de-identified data. As the Department of Health and Human Services noted in its commentary supporting HIPAA:

Large data sets of de-identified information can be used for innumerable purposes that are vital to improving the efficiency and effectiveness of health care delivery, such as epidemiological studies, comparisons of cost, quality or specific outcomes across providers or payers, studies of incidence or prevalence of disease across populations, areas or time, and studies of access to care or differing use patterns across populations, areas or time.

Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59918, 59946 (proposed Nov. 3, 1999).

These benefits are not just theoretical. Researchers and government officials have, on numerous occasions, used de-identified health information to benefit the public health. The National Committee for Quality Assurance ("NCQA"), for example, uses de-identified health care information to monitor variations in quality of care. In one remarkable example, the use of de-identified health information led to more than 97% of patients who suffered heart attacks being prescribed beta-blockers to help prevent a second attack, up from only 62% in 1996. This improvement alone saved between 4,400 and 5,600 lives over the past six years. NCQA, *The State of Health Care Quality 2007* 10, 26 (2007).

Further, the risk to patient privacy as a result of transferring de-identified data under HIPAA generally arises from efforts to re-identify patients using the data. In this regard, while HIPAA privacy protections could be strengthened, this would be achieved by strengthening prohibitions against re-identification of de-identified data. But the Prescription Information Law does no such thing. Rather, the statute throws the baby out with the bathwater – prohibiting the transfer of de-identified information for *commercial* purposes – a limitation that has nothing to do with preventing re-identification of patient information.

Review of the Prescription Information Law is therefore critical to facilitate the national interest in enhancing the flow and use of health care information

where, as here, it does not implicate any legitimate privacy interest.

II.

THIS COURT SHOULD GRANT THE PETITION FOR A WRIT OF CERTIORARI BECAUSE THE NEW HAMPSHIRE STATUTE WILL STIFLE EFFORTS TO EVALUATE AND IMPROVE HEALTH CARE QUALITY THROUGH HEALTH INFORMATION TECHNOLOGY

The use of health information technology, or health IT, is one of the most important developments in modern health care. Health IT encompasses the trend in the health care sector to collect, exchange, aggregate, analyze, and communicate health information electronically. Health IT offers providers quick and reliable access to needed patient information, and thus improves care. Thus health IT is not an end unto itself, but rather is a means of improving the quality of health care.

With the advent of health information technologies like electronic health records that facilitate information sharing among providers at the point of care, we are at the tipping point when it comes to our ability to evaluate and improve provider performance, and therefore care of patients. To make health care delivery better, safer, more efficient, and less prone to medical errors, we need to know more – not less – about what physicians and other health care providers do. Much of what we need to know to

accomplish these aims can be served by using de-identified data, which can be collected, analyzed, exchanged, and communicated electronically to those who would rely on it to improve care, thanks to advances in health information technology.

The potential for health IT to improve patient care and health care quality is particularly compelling. Remarkably, more Americans die each year from preventable medical errors than from AIDS or breast cancer. Institute of Medicine, *To Err Is Human: Building a Safe Health System* (1999). Indeed, the NCQA reports between 35,000 and 75,000 avoidable deaths, and between \$2.7 billion and \$3.7 billion in avoidable hospital costs in the year 2006 due to unexplained variations in quality of care. NCQA, *The State of Health Care Quality 2007* 12 (2007). Further, while substantial investments have been made in clinical research and development over the last 30 years, resulting in an enormous increase in medical knowledge, a 15 to 20 year lag exists before physicians incorporate this knowledge into their care. E.A. Balas and S.A. Boren, *Managing Clinical Knowledge for Health Care Improvement*, in *IMIA Yearbook of Medical Informatics* 65-70 (2000). Health IT can reduce this lag. As the Institute of Medicine stated, "[t]o deliver care in the 21st century, the [health care] system must have a health information and communications technology infrastructure that is accessible to all patients and providers." Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001).

In recognition of both the importance of health IT to delivering quality health care and its potential economic benefits, President Obama recently included in the federal stimulus package approximately \$36 billion to network the health care industry so that it can deliver high-quality efficient patient care.⁴ But the President is only the most recent leader to recognize the enormous potential of health IT to bring transparency to the health care system and improve patient care. Indeed, a 2006 report noted that President Bush, both parties' congressional leaders, and nearly 40 states' governors and state legislatures had begun to pursue major health IT initiatives, to achieve greater value for health care spending. See eHealth Initiative, *eHealth Initiative Issue Brief: States Getting Connected: State Policy-Makers Drive Improvements in Healthcare Quality and Safety Through IT* (2006). These leaders want to use health IT to save lives, and they want patients to make health care decisions armed with information about the cost and quality of the services they are buying.

But the New Hampshire law – and others like it – threatens to undermine the access to information that will drive these reforms. While the First Circuit construed the Prescription Information Law to prohibit only the transfer of prescription information

⁴ See Letter dated February 13, 2009 from Congressional Budget Office to Speaker of the House of Representatives Nancy Pelosi at Table 2, available at <http://www.cbo.gov/doc.cfm?index=9989> (last viewed April 23, 2009).

used for the purposes of detailing, the language of the statute is considerably broader. Rather than directly regulating the conduct of detailers in connection with pharmaceutical company marketing efforts, the law *criminalizes* the transfer of "prescription information containing . . . prescriber-identifiable data . . . for *any commercial purpose*." The term "commercial purpose" is defined as "*any* activity that could be used to influence or even to evaluate the prescribing behavior of physicians."

Moreover, while the statute contains several exceptions, none are clearly defined. Thus, with limited, undefined, and amorphous exceptions, the law prohibits pharmacies, benefits managers, insurance companies, and the like from selling "for any commercial purpose" information about prescriptions written by New Hampshire prescribers.

Health IT is the key to facilitating the flow of information to both patients and physicians that will enable improvements in health care. But an overbroad statute, with poorly defined exceptions will have a chilling effect on the development of health IT. This effect is overwhelming when one considers that a number of other states are considering similarly broadly worded statutes, with poorly defined prescriptions, and indeterminate exceptions. Moreover, while the First Circuit read the Prescription Information Law to proscribe only the transfer of prescriber information for the purposes of detailing, there is no guarantee that other courts – including New Hampshire courts applying the law – will read

the statute the same way. Nor will other courts reviewing other states' statutes be held to the First Circuit's interpretation of the New Hampshire enactment.

The development of a national "health information superhighway" that is facilitated through health IT – an enterprise that is inherently interconnected and national in scope – will be choked if, in order to do business, companies have to wade through a morass of state statutes with unclear prohibitions and exceptions. Indeed, this Court's jurisprudence under the Commerce Clause already has recognized that where an industry is not "admitting of diversity of treatment, according to the special requirements of local conditions" a State requirement that is "out of line with the requirements of almost all the other States" may place an undue burden on interstate commerce. See *Bibb v. Navajo Freight Lines*, 359 U.S. 520, 529-30, 79 S. Ct. 962, 3 L. Ed. 2d 1003 (1959); see also *CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69, 88, 95 L. Ed. 2d 67, 107 S. Ct. 1637 (1987) ("This Court's recent Commerce Clause cases also have invalidated statutes that may adversely affect interstate commerce by subjecting activities to inconsistent regulations.").

Review of this case is vital. The development of health IT will improve access to health care information for patients, providers and researchers. It will save lives. The New Hampshire Prescription Information Law – and others like it – threaten to stifle the development of this technology by requiring

patients and industry to navigate a patchwork of state regulatory regimes with vague statutes regarding access to de-identified health data, and at least in the case of New Hampshire, risk *criminal* penalty should they run afoul of one of these regimes.

CONCLUSION

Review by this Court is imperative. The New Hampshire Prescription Information Law may have been the brainchild of good intentions. Still, it will impair the development of health IT and the essential use of de-identified health information to improve access to information, save lives, and reduce risks endemic to the health care system.

By justifying the statute on “privacy” grounds, the State has incorrectly presumed that prescribers have a privacy interest in their medical practices. But prescribers, who work in a highly-regulated industry, have no expectation of privacy in their medical practice, and federal law already provides rigorous standards for de-identifying patient health care information to protect patient privacy interests.

While States may provide privacy protection for patient health information that is greater than the federal floor HIPAA sets, the New Hampshire statute – which regulates *de-identified* information – simply doesn’t do so. Instead, it subjects the collection of critical health data using health IT to a thicket of vague, perhaps inconsistent local regulations. Thus,

the New Hampshire Prescription Information Law – and others like it – will impair the development of the technology, leading to less access to information, and enormous public health consequences.

Respectfully submitted,

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IN THE
Supreme Court of the United States

IMS HEALTH, INC. *et al.*,

Petitioners,

v.

AYOTTE,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

**BRIEF OF THE COALITION FOR HEALTHCARE
COMMUNICATION AS *AMICUS CURIAE*
IN SUPPORT OF PETITIONERS**

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INTEREST OF *AMICUS CURIAE*¹

Amicus the Coalition for Healthcare Communication ("CHC") comprises trade associations and their members who engage in medical education, publishing, and marketing of prescription products and services, including drugs, devices, and biologics. Trade association members include the American Association of Advertising Agencies and the Association of Medical Media. These members make extensive use of prescriber-identifiable data that enable them to increase the effectiveness and efficiency of education and communication programs on behalf of the manufacturers of prescription products. The suppression of these data would interfere substantially with the ability of member companies to meet their clients' needs, educate prescribers, and improve patient care. Moreover, a ban on commercial use of these data will effectively eliminate their availability for the non-commercial research, public policy planning, and safety uses in which CHC members participate. Thus, the CHC has a considerable interest in the outcome of this case.

1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae*, or its counsel made a monetary contribution to its preparation or submission. Counsel for *amicus* also represent that counsel of record for all parties received notice of *amicus*'s intention to file this brief at least 10 days prior to the due date. The parties have filed written global consent to the filing of *amicus* briefs with the Clerk of the Court.

SUMMARY OF ARGUMENT

New Hampshire's Prescription Restraint Law (or "new law") prohibits, with important and discriminatory exceptions, the sale or use of prescriber-identifiable prescription data "for any commercial purpose," including "*advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product.*" N.H. Rev. Stat. Ann. §§ 318:47-f, 318-B:12, IV (2006) (emphasis added). The legislative intent and purpose of the new law is to limit the efficiency and effectiveness of pharmaceutical marketing by innovator, branded drug manufacturers by denying them access to the tools that help them shape effective messages, without overtly restricting their access to the medical community. The State speculates that this restraint might cause New Hampshire physicians to more often prescribe older, generic drugs instead of newer, branded drugs, and thereby reduce total prescription drug costs borne by individual New Hampshire residents. The State seeks to advance this paternalistic interest by blunting the effectiveness of truthful and non-misleading commercial speech whose objective the State disfavors.

Not only does the new law infringe upon the CHC members' and pharmaceutical manufacturers' commercial speech rights, it also has the (perhaps unintended, but still very real) effect of potentially curtailing non-commercial communications among and between numerous other entities that have no discernible impact on cost containment. As Petitioners explain, *see* Pet. 3, and as the CHC has maintained throughout this litigation, the revenue generated by the

sale of prescriber-identifiable data to pharmaceutical companies for the purpose of detailing enables data collection companies to provide the same data at little or no cost to a variety of public health and research entities. Pet. 3. More directly, the scope of the new law's prohibition includes use by CHC's members to craft marketing and other communications to physicians to promote privately administered continuing medical education ("CME") programs, public relations, and advertising in medical journals. Thus, the new law outruns the State's alleged cost containment rationale by sweeping within its ambit an unreasonably broad array of constitutionally protected and socially valuable communications.

The district court held, consistent with this Court's First Amendment jurisprudence, that the new law imposes an unconstitutional restraint on commercial speech. *See* Pet. 5-6. The First Circuit reversed, basing its decision on two alternative—and equally suspect—holdings. *See id.* at 5-9. *First*, the First Circuit reviewed the new law outside the ambit of the First Amendment based on its ostensible regulation only of conduct, *i.e.*, the sale of prescriber-identifiable data to pharmaceutical companies for purposes of detailing, and not speech. *Id.* at 6-7. In order to shut its eyes to the new law's intended effect on manufacturer speech, the majority chose to seize upon the absence of manufacturer plaintiffs to employ an erroneous and pernicious theory of prudential standing and cabin the First Amendment inquiry to the upstream sale of prescriber-identifiable data. *See IMS Health, Inc. v. Ayotte*, 550 F.3d 42, 64-65 (1st Cir. 2008) (Lipez, J., concurring and dissenting). Thus, the First Circuit's primary majority holding refused to take

account of the fact that the purpose of the new law is to use a restraint on the upstream sale of data to curb the speech of detailers—and that it has succeeded in having this nefarious impact. *Second*, the First Circuit held, in the alternative, that even if the new law were viewed as regulation of commercial speech, it would survive intermediate scrutiny. Pet. 7. Judge Lipez concurred in part and dissented in part, taking the view that the purpose and impact of the new law on pharmaceutical company speech triggers First Amendment scrutiny, but concurring in the majority's conclusion that the new law passes constitutional muster under the analysis established by this Court in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980). See Pet. 9-10.

CHC believes that the First Circuit committed fundamental errors in upholding the new law against the Petitioners' constitutional challenge. Unless, contrary to 40 years of Supreme Court constitutional precedent, the State may suppress commercial speech at its whim, it cannot constrain truthful and non-misleading speech simply because it has become, in the State's view, too persuasive in delivering a disfavored commercial message to physician audiences. The fact that the State seeks to achieve its goal by depriving commercial speakers of the information necessary to tailor their messages to audience concerns, rather than to deny access to the audience itself should not—and under the Supreme Court's precedent, does not—shield it from First Amendment scrutiny.

For four decades, the Supreme Court has repeatedly struck down under the First Amendment government

attempts to place restrictions on advertising, marketing, and commercial solicitation.² In doing so, the Court has explained that:

The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. Thus, even a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment.

Thompson v. W. States Med. Ctr., 535 U.S. 357, 367 (2002) (quoting *Edenfield v. Fane*, 507 U.S. 761, 767 (1993)). Contrary to the judgment of the First Circuit, New Hampshire's new law violates this fundamental constitutional tenet and thus must suffer a similar fate. By seeking to hobble speakers who wish to effectively introduce truthful communications into the marketplace

2. See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (soliciting of compounded pharmaceutical drugs); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (tobacco and cigar advertisements near schools and playgrounds); *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173 (1999) (legal gambling advertisements); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) (alcoholic beverage advertisements); *Edenfield v. Fane*, 507 U.S. 761 (1993) (in-person solicitation by accountants); *Va. Bd. Of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) (advertising and marketing of pharmaceutical drugs).

of ideas, the new law strikes at the very heart of the First Amendment. *See id.* at 366-67.

REASONS FOR GRANTING THE PETITION

Amicus curiae the CHC agrees with the Petitioners' arguments as to why the First Circuit's judgment upholding the new law warrants review. *See* Pet. 11. Additionally, CHC submits that review is warranted because the First Circuit's judgment is in two critical respects in direct and irreconcilable conflict with the Supreme Court's First Amendment jurisprudence.

I. The First Circuit's Holding, Contrary To This Court's Precedent, That A State May Avoid First Amendment Scrutiny Of Speech Restraints By Targeting The Tools That Make Disfavored Speech Effective Warrants Review.

The First Circuit's primary holding—that the new law is not subject to the strictures of the First Amendment because it bans only the sale of the data that enable detailers to make their disfavored commercial speech effective—perniciously insulates the state's goal of indirectly suppressing speech based on its content. This holding is both deeply troubling and contrary to this Court's precedent.

On its face, the new law restricts the commercial speech of detailers by banning access to a tool that makes their speech more effective, *i.e.*, the use of prescriber-identifiable data to tailor targeted commercial communications to the interests and patient

populations of New Hampshire physicians.³ The new law provides that prescription records containing such data “shall not be licensed, transferred, used, or sold . . . for any commercial purpose,” where “commercial purpose” is defined to include, among other things, “*advertising, marketing, promotion*, or any activity that could be used to influence sales or market share of a pharmaceutical product . . . or evaluate the effectiveness of a professional pharmaceutical detailing sales force.” N.H. Rev. Stat. Ann. § 318:47-f (2006) (emphasis added). By its terms—“advertising,” “marketing,” and “promotion”—the new law thus directly targets commercial speech and forecloses access to prescriber-identifiable data to tailor marketing communications.

The purpose of the new law is not to protect the privacy of patients, who are not identified in the relevant data. *See* Pet. 2-3. Nor is the new law aimed at preventing the dissemination of false or misleading information about prescription drugs—an interest vindicated by other laws. 21 C.F.R. § 202.1(e)(5)-(6); *see also New Hampshire v. Moran*, 861 A.2d 763, 765-66 (N.H. 2004) (explaining New Hampshire legal restrictions on unfair

3. Indeed, even as between the sales representative and prescriber, the communications at issue are at the very least a mix of commercial speech and fully protected scientific communications. *See, e.g., Miller v. California*, 413 U.S. 15, 34 (1973) (“The First Amendment protects works which, taken as a whole, have serious literary, artistic, political, or *scientific* value.” (emphasis added)); *Bd. of Trs. of Leland Stanford Junior Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991) (“It is . . . settled . . . that the First Amendment protects *scientific expression and debate* just as it protects political and artistic expression.” (emphasis added)).

or deceptive actions); *see generally* 21 U.S.C. §§ 332-337. Rather, and as the State has consistently admitted, the purpose, design, and effect of the new law is to hamper targeted marketing to prescribers. As the text and legislative history of the new law demonstrate, and the State conceded below, the provision is clearly aimed at “the speaker’s ability to propose a commercial transaction and the adult listener’s opportunity to obtain information about products;” it is a restriction focused on the content of commercial speech. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 565 (2001); *see also* *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976) (singling out speech of a particular content (pharmacist price advertising) and seeking to prevent its dissemination completely cannot be given reduced scrutiny as a time, place, and matter restriction); *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173 (1999) (legal gambling broadcast advertisements); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) (alcoholic beverage prices); *Edenfield*, 507 U.S. 761 (in-person solicitation by accountants); *W. States*, 535 U.S. 357 (solicitation of compounded pharmaceutical drugs).

The First Circuit majority’s myopic insistence on analyzing the new law as a regulation of conduct, notwithstanding the State’s express goal of undermining the effectiveness of detailers’ marketing speech, is possible only because of the majority’s unprincipled manipulation of prudential standing principles. *See IMS Health*, 550 F.3d at 48-49; *see also id.* at 65-69 (explaining how “[t]he majority’s use of standing principles is . . . doubly wrong”). The majority explained that the new law regulates the acquisition of prescriber-identifiable

data and the sale of that data to pharmaceutical companies, but does not directly regulate the use of the data by detailers to tailor messages to their physician audiences. *Id.* at 48-49. Because “[n]o pharmaceutical company, detailer, or physician is a party to this case,” *id.* at 49, the majority confined its constitutional analysis to the first two transactions, without regard to the legislature’s avowed intent to restrict the speech of detailers or the fact that the new law has succeeded in having its desired impact. As Judge Lipez ably explains, the majority’s use of prudential standing principles is unjustified, *see id.* at 67, and results in an imprudent avoidance of facts material to full consideration of the constitutional issues, *see id.* at 68.⁴

When the First Circuit’s allegedly prudential analytical restriction is removed, it is apparent that the new law runs directly contrary to Supreme Court precedent, which has “explicitly held that commercial speech receives First Amendment protection.” *W. States*, 535 U.S. at 366. Indeed, the First Amendment incontrovertibly protects the type of speech explicitly targeted by the new law, including the right of pharmaceutical manufacturers to specially tailor direct-mail and in-person solicitations through detailers. *See, e.g., Edenfield*, 507 U.S. at 765-67 (invalidating state’s attempt to ban personal solicitation of clients by accountants); *W. States*, 535 U.S. at 365-66 (holding unconstitutional FDCA amendments requiring prescriptions for compounded drugs to be “unsolicited”

4. This Court should grant *certiorari* to make clear that when a provider of tools essential to effective speech is directly injured by a restraint targeted on the content of that speech, First Amendment scrutiny is prudentially essential.

and that pharmacists “not advertise or promote the compounding of any particular drug, class of drug, or type of drug” (quoting 21 U.S.C. § 353a(c)); *Pac. Frontier v. Pleasant Grove City*, 414 F.3d 1221, 1231 (10th Cir. 2005) (noting that “[t]he Supreme Court has recognized that personal solicitation is imbued with important First Amendment interests” and enjoining restriction on door-to-door solicitations (citations omitted)).

The new law also infringes upon the right of willing listeners, here prescribing physicians, to receive targeted commercial communications. As this Court has recognized, “[f]reedom of speech presupposes a willing speaker. But where a speaker exists, as is the case here, the protection afforded is to the communication, to its source and to its recipients both.” *Va. State Bd. of Pharmacy*, 425 U.S. at 756-57; see also *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232 (10th Cir. 1999) (“Effective speech has two components: a speaker and an audience. A restriction on either of these components is a restriction on speech.”). As the Supreme Court has explained time and again, “‘the free flow of commercial information is indispensable’ . . . [and] a ‘particular consumer’s interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day’s most urgent political debate.’” *W. States*, 535 U.S. at 366-67 (quoting *Va. Bd. of Pharmacy*, 425 U.S. at 763).

The fact that the State has attacked the tools through which marketers make their communications effective, rather than barring access to the audience, does not remove the new law from constitutional

scrutiny. *See, e.g., Boos v. Barry*, 485 U.S. 312, 321 (1988) (explaining that “[r]egulations that focus on the direct impact of speech on its audience” are subject to First Amendment scrutiny); *Grosjean v. Am. Press Co.*, 297 U.S. 233, 249 (1936) (invalidating taxes on press and explaining that the Court has been “careful not to limit the protection of the right [to free speech and press] to any particular way of abridging it”). Indeed, New Hampshire’s law is conceptually no different from denying an unpopular political group access to polling data. *See, e.g., R.I. Ass’n of Realtors, Inc. v. Whitehouse*, 51 F. Supp. 2d 107, 111 (D.R.I. 1999) (acknowledging that “[c]ommercial solicitation is a form of commercial speech protected by the First Amendment” and invalidating prohibition against use of information obtained from public records “to solicit for commercial purposes” (citing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 75 (1983))); *U.S. West, Inc.*, 182 F.3d 1224 (striking down on First Amendment grounds the FCC’s restriction on communications carriers’ ability to use a customer’s information to target market services to that customer); *Verizon Nw., Inc. v. Showalter*, 282 F. Supp. 2d 1187, 1191 (W.D. Wash. 2003) (same for Washington law).

The new law is also conceptually similar to a restriction on the use of a forum or medium of communication. *See, e.g., Schneider v. New Jersey*, 308 U.S. 147 (1939) (holding that government may regulate conduct in public fora provided it does not regulate conduct that “bears [a] necessary relationship to the freedom to speak, write, print or distribute information or opinion”). This Court has consistently held that even a generally applicable, content neutral regulation of a

forum may run afoul of the First Amendment if it has the practical effect of wholly depriving speakers of an effective medium of communication with willing listeners. *See, e.g., City of Ladue v. Gilleo*, 512 U.S. 43, 54 (1994) (invalidating sign ordinance because government had “almost completely foreclosed a venerable means of communication that is both unique and important”); *Saia v. New York*, 334 U.S. 558, 561 (1948) (invalidating law requiring permit for the use of sound amplification equipment, explaining that “[l]oud-speakers are today indispensable instruments of effective public speech”). The constitutional violation in this case is more stark than in many forum regulation cases because New Hampshire has not only deprived detailers of “a venerable means of communication that is both unique and important,” *Gilleo*, 512 U.S. at 54, but has done so in a manner that is transparently content-based, *see, e.g., City of Cincinnati v. Discovery Network*, 507 U.S. 410, 429-30 (1993) (“It is the absence of a neutral justification for its selective ban on newsracks that prevents the city from defending its newsrack policy as content neutral.”).

As Petitioners explain, *see* Pet. 10-11, the First Circuit’s failure to faithfully adhere to this Court’s precedent subjecting indirect content-based commercial speech restrictions to First Amendment scrutiny poses significant dangers to the freedom of speech. Thus, review is warranted to vindicate decades of established First Amendment jurisprudence and prevent the proliferation of laws suppressing disfavored speech by depriving the targeted speakers of the tools necessary to make their message most effective.

II. The First Circuit's Alternative Holding, Contrary To This Court's Precedent, That Limiting The Effectiveness Of Disfavored Commercial Speech Is A Substantial State Interest Independently Warrants Review.

The First Circuit's alternative holding that the new law passes constitutional muster under the intermediate scrutiny applicable to commercial speech regulations is also contrary to this Court's precedent. *See* Pet. 24-37. In particular, it stands as a novel and dangerous sanction of the notion that the State has a substantial interest in preventing or inhibiting speakers from persuading their audiences of a truthful but disfavored message. New Hampshire's asserted interest in "cost containment" is not proprietary. The State has unquestioned alternatives for directly limiting its prescription drug expenditures. Rather, the State is asserting a paternalistic interest to justify restraining truthful and non-misleading speech as a means of controlling individual citizen behavior. That is the essence of censorship, and censorship is no less pernicious when it forecloses informed commercial choices than it is when it forecloses informed political choices.

Under *Central Hudson*, if commercial speech is not misleading and does not concern unlawful activity, "it can only be limited if the restriction (1) is in support of a substantial government interest, (2) 'directly advances the governmental interest asserted,' and (3) 'is not more extensive than is necessary to serve that interest.'" *El Día, Inc. v. Puerto Rico Dep't of Consumer Affairs*, 413 F.3d 110, 113 (1st Cir. 2005) (quoting *Central*

Hudson, 447 U.S. at 566). The CHC agrees with the Petitioners' articulation of why the First Circuit erred in its evaluation of the new law under this well-established test, *see* Pet. 24-37, and further urges that the First Circuit's treatment of the substantial government interest prong of the test is sufficiently erroneous in itself to warrant review.

As explained above, the motivation behind the new law is to affect prescriber behavior by inhibiting the flow of information to them. A State's interest in removing truthful information from the marketplace of ideas because it is persuasive is simply not a constitutionally legitimate one, regardless of whether the purpose is characterized as eliminating effective drug "detailing" or effectuating indirect cost controls. *44 Liquormart*, 517 U.S. at 501; *Meyer v. Grant*, 486 U.S. 414, 424 (1988) ("The First Amendment protects [the speaker's] right not only to advocate their cause but also to select what they believe to be the most effective means for so doing."); *Shapero v. Ky. Bar Ass'n*, 486 U.S. 466, 473-74 (1988) ("[T]he First Amendment does not permit a ban on certain speech merely because it is more efficient"); *U.S. West*, 182 F.3d at 1232 ("[A] restriction on speech tailored to a particular audience, 'targeted speech,' cannot be cured by the fact that a speaker can speak to a larger indiscriminate audience, 'broadcast speech.'"); *Project 80's, Inc. v. City of Pocatello*, 942 F.2d 635, 639 (9th Cir. 1991) ("[O]ptions that involve 'more cost and less autonomy' to the seller, that are less likely to reach those persons 'not deliberately seeking sales information,' and that may be less effective media for communicating the message, 'are not satisfactory substitutes for speech that is prohibited.'" (quoting

Linmark Assocs., Inc. v. Township of Willingboro, 431 U.S. 85, 93-94 (1977)).

This Court has never permitted the inhibition of commercial speech on the ground that it is too persuasive. To the contrary, the Court has repeatedly “rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information,” and has adhered to this position specifically with respect to restrictions in the medical and pharmaceutical realm. *W. States*, 535 U.S. at 374 (explaining that fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway “rests on the questionable assumption that doctors would prescribe unnecessary medications” (citing *Va. Bd. of Pharmacy*, 425 U.S. at 769 (rejecting restriction on pharmacist price advertising supported by purported interests in preventing people from choosing “the low-cost, low-quality service and driv[ing] the ‘professional’ pharmacist out of business” and preventing the destruction of the “pharmacist-customer relationship”))); see also *Lorillard*, 533 U.S. at 565 (“[A] speech regulation cannot unduly impinge on the speaker’s ability to propose a commercial transaction and the adult listener’s opportunity to obtain information about products.”). In short, the First Circuit’s judgment fails to heed this Court’s admonition that “[t]he First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.” 44 *Liquormart*, 517 U.S. at 503.

Prior to the First Circuit's judgment in this case, there was not a single case that could be cited in support of the notion that a speech restriction can be upheld because the speech at issue is too effective at persuading a consumer—here an educated and licensed medical care provider—to engage in permissible activity. A paternalistic desire to have consumers, let alone industry professionals, make different market choices among goods and services is not the type of interest that can sustain a restriction on truthful and non-misleading commercial speech. As the Court explained three decades ago in striking down an advertising measure in which cost-control was identified as an interest served, *Va. Bd. of Pharmacy*, 425 U.S. at 767-68, the significance of the proffered interest must not be judged in a vacuum but in light of the protections of the First Amendment, *id.* at 768-69. "This casts the Board's justifications in a different light, for on close inspection it is seen that the State's protectiveness of its citizens rests in large measure on the advantages of their being kept in ignorance." *Id.* at 769.

Review is thus warranted to prevent the proliferation of laws that "completely suppress the dissemination of concededly truthful information about entirely lawful activity, [merely out of] fear[] of that information's effect upon its disseminators and its recipients." *Id.* at 773; *cf. Hill v. Colorado*, 530 U.S. 703, 716 (2000) ("The right to free speech, of course, includes the right to attempt to persuade others to change their views, and may not be curtailed simply because the speaker's message may be offensive to his audience."). In short, the fact that the State does not like the market choices consumers, here licensed prescribers, are

making in response to the commercial speech activities of detailers has never been—and should not now be—recognized as a substantial government interest.

CONCLUSION

For the foregoing reasons, the Court should grant the petition and reverse the decision of the First Circuit.

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No. 08-1202

Supreme Court, U.S.
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**In The
Supreme Court of the United States**

IMS HEALTH, INC. and VERISPAN LLC,

Petitioners,

v.

KELLY M. AYOTTE, as Attorney General
of the State of New Hampshire,

Respondent.

**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The First Circuit**

**BRIEF OF COUNCIL OF AMERICAN
SURVEY RESEARCH ORGANIZATIONS, INC.
AND PHARMACEUTICAL MARKETING
RESEARCH GROUP, INC. AS AMICI CURIAE
SUPPORTING THE PETITIONERS'
PETITION FOR WRIT OF CERTIORARI**

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INTERESTS OF AMICI CURIAE¹

Council of American Survey Research Organizations, Inc. ("CASRO").

CASRO is a not-for-profit trade association representing over three hundred (300) United States survey research companies engaged in professional survey research regarding a wide variety of technical, scientific, pharmaceutical, health care, economic, and other public and private issues. The survey research companies' clients include virtually every manner of for-profit, not-for-profit and governmental entity. See Appendix A. CASRO's members are in aggregate responsible for the overwhelming majority of the survey research, including pharmaceutical survey research, conducted each year in the United States. CASRO was formed for the purposes of creating certain values and standards for the survey research industry and establishing a spokesperson to represent the interests of the survey research industry. CASRO's principle functions are (1) to promote a rigorous code of conduct that enhances the image of survey research and protects the public's rights and privacy; (2) to advocate the survey research industry's effective

¹ All counsel of record received written notice of Amici's intention to file this brief, at least ten (10) days before this brief was due. This brief is filed with the written consent of all parties, which consents are filed herewith. No counsel for any party authored this brief, whether in whole or in part, nor did any person or entity, other than Amici or their counsel, make a monetary contribution to the preparation of this brief.

self-regulation when legislators propose bills that threaten legitimate survey research; and (3) to champion legitimate research companies and marginalize disreputable research companies that threaten or attempt to threaten the survey research industry's reputation. See Appendix A. A vast majority of CASRO's members work, whether directly or indirectly, with the pharmaceutical, medical and health care industries conducting legitimate survey research designed to improve treatment options and patient care; and improve and develop pharmaceutical products and medical devices. This case and its proper resolution are of great importance to CASRO, as upholding the New Hampshire Prescription Information Law (*see* 2006 N.H. Laws § 328, *codified at* N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006) (referred to hereinafter as the "Prescription Information Law")) would (1) threaten the legitimate business activities of Petitioner IMS Health, Inc., a CASRO member; (2) threaten legitimate pharmaceutical survey research by eliminating a valuable information and data resource; and (3) threaten the permitted uses of other reliable, truthful and lawfully obtained information, which, similar to the data and information at issue in this case, are essential to CASRO and its membership in the performance of legitimate survey research, including without limitation pharmaceutical survey research. Additional information about CASRO can be found at <http://www.casro.org/>.

Pharmaceutical Marketing Research Group, Inc. ("PMRG")

PMRG is a not-for-profit trade association whose members consist of over eight hundred (800) individual employees of (a) marketing research companies and (b) manufacturers of pharmaceutical, biotech, medical device and other health care products who commission the services of such research companies. PMRG's purpose is to promote the use and quality of marketing research for and by such manufacturers (referred to generally herein as "pharmaceutical marketing research," and for present purposes generally tantamount to pharmaceutical survey research). PMRG'S principal activities consist of (1) providing educational and other collaborative forums where employees of such manufacturers and their marketing research suppliers meet; (2) promoting technical knowledge and ethical standards for the conduct of pharmaceutical marketing research; and (3) advocating on government affairs issues of concern to PMRG's membership. PMRG considers pharmaceutical marketing research to be of great positive social impact. Among many other benefits to American society, pharmaceutical marketing research has been a significant driver in the development and improvement of medical devices, drugs and services. Many life-improving and life-saving solutions owe their existence to such research, whether through the creation of new products or through better delivering existing treatments. Many (individual) researcher-side members of PMRG are employed by (corporate)

members of CASRO, including by Petitioner IMS Health, Inc., while several PMRG members are employed by Petitioner Verispan LLC's parent, SDI Health LLC. This case and its proper resolution are of importance to PMRG for the same reasons they are important to CASRO, as stated above. Additional information about PMRG can be found at <http://www.pmr.org/>.

The Survey Research Industry

The survey research industry, of which Amici and their membership are a part, is a well respected and important fixture of the commercial landscape that is essential to the development and improvement of health care in the United States and other countries. Survey research serves an important function throughout our society² and is utilized by universities (in the fields of medicine and social sciences, for example), corporations, research institutes, litigants, as well as governmental agencies, to assist in the analyses of technical, scientific, economic, health care, pharmaceutical, and other social, commercial,

² See generally M. Finkelstein, *Quantitative Methods in Law* (1978), quantitative techniques of proof as applied in various legal claims; H. Barksdale, *The Use of Survey Research Findings as Legal Evidence* (1957) (same); W. Finfrock & D. Spradlin, *How to Organize and Present Statistical Evidence*, 24 *Prac. Law.* 67, 67-68 (1978), antitrust evidence increasingly economic and statistical; I. McCarthy, *Trademarks and Unfair Competition*, Section 32:46 ff. (2d ed. 1984), important and growing role of survey evidence.

scientific and public policy issues. No other tool permits these societal constituencies to obtain comparable data and related information. Without such data many issues affecting both public and private interests could not be addressed as intelligently or resolved as reliably. There is, as one court rightly summarized the situation, "undoubtedly a compelling social interest in promoting [survey] research." *Andrews v. Eli Lilly & Co.*, 97 F.R.D. 494, 500 (N.D. Ill. 1983). See also, *Dow v. Allen*, 672 F.2d 1262 (7th Cir. 1982). In *Cimino v. Raymark Industries, Inc.*, 751 F. Supp. 649 (E.D. Tex. 1990), the court articulated the value of survey data as a unique and important research tool:

"... the science of statistics is now universally accepted, exerting the most profound influence on our daily lives. 'The objective of statistics is to make an inference about a population of interest based on information obtained from a sample ... of that population.' For example, statistical sampling plays a critical role in medical and pharmaceutical research ... [a]s in medical research, private industries employ statistical techniques in the development and testing of new products ... [it is used] for many diverse tasks, such as maintaining the dimension requirements for the plastic cards used in automatic bank teller machines or testing the specific gravity of laundry detergent. Statistical techniques are particularly valuable in the field of marketing ... the insurance industry ... education ... in the

administration and evaluation of various standardized tests . . . [and] in the political arena." *Id.* at 660.

The judicial process itself is a significant beneficiary of survey and public opinion research. In *Cimino*, it was reported that " . . . [a]cceptance of statistical evidence is now commonplace in the courts . . . , it occurs frequently in Title VII employment discrimination cases, most often demonstrating a pattern or practice of discrimination on the part of the employer . . . , it has been used in anti-trust cases to project pre and post merger market share and market concentration. . . . [and] in trademark infringement suits [it] is useful in determining consumer product identification and confusion regarding trademarks. . . ."

SUMMARY OF ARGUMENTS

The Prescription Information Law and the decision of the United States Court of Appeals for the First Circuit (the "First Circuit") (1) lay the foundation for the unfair and legally improper termination of the Petitioners' subject lines of business – not only in New Hampshire, but throughout the United States, as two additional states currently have enacted laws restricting the use of prescriber-identifiable and patient-identifiable information, and numerous other state legislatures have proposed and are considering similar legislation during this current legislative calendar period, all as a direct result of the Prescription Information Law, for the sole purpose of placing

restrictions on the communications between pharmaceutical detailers³ and physicians; (2) fail to consider the varied uses of, and varied businesses and industries relying on and benefiting from, prescriber-identifiable information; and (3) open the door for unchecked governmental regulation of other forms and types of reliable, legitimate and truthful speech (i.e. reliable, legitimate, and truthful information), which would have a devastating effect on businesses and industries relying on the availability of such information and on the general public who are the beneficiaries of the products and services provided by such businesses and industries. Amici, therefore respectfully request this Court to grant the Petitioners'

³ The subtle differences in the explanations of "detailing" as described in the First Circuit's Majority Opinion and Judge Lipez's Concurring/Dissenting Opinion highlight the differing societal value placed on "detailing." The Majority Opinion explains detailing as follows: "Pharmaceutical sales representatives, known in industry argot as 'detailers,' earn their livelihood by promoting prescription drugs in one-on-one interactions with physicians." *IMS Health, Inc. v. Kelly A. Ayotte*, 550 F.3d 42, 44 (1st Cir. 2008). The Majority Opinion further elaborates that "If a physician's prescribing habits present an appropriate opportunity, the detailer attempts to gain access to the physician's office, usually by representing herself as a helpful purveyor of pharmaceutical information and research." *IMS Health, Inc.* at 46. Judge Lipez's Concurring/Dissenting Opinion explains "detailing" as follows: "Detailing is the face-to-face advocacy of a product by sales representatives who visit doctors' offices and hospitals to meet with prescribing health care professionals. Although the objective of these visits is to make sales, detailers often provide valuable information about the drugs they are selling." *Id.* at 71.

writ of certiorari and reverse the First Circuit's ruling.

ARGUMENTS

I. The Prescription Information Law and the First Circuit's Ruling Effectively Terminate the Petitioners' Subject Lines of Business For the Sole Purpose of Placing Restrictions on Communications Between Pharmaceutical Detailers and Physicians.

The Petitioners are in the pharmaceutical market intelligence business, an area of pharmaceutical market research, and they provide certain products and services that address a variety of needs within the pharmaceutical, medical and health care industries. As noted above, Petitioner IMS Health, Inc. is a valued member of Amicus CASRO in good standing, and to CASRO'S knowledge it upholds CASRO's standards of professional and ethical conduct. The products and services at issue in this case involve the Petitioners' purchase of reliable, legitimate and truthful information (i.e. prescriber-identifiable information) from pharmacies and other sources; the deletion or removal of any data or information that may identify an individual patient; the aggregation of the prescriber-identifiable information with other information that is either available to the general public or obtained through a license with a third party, but that in any event is likewise

devoid of patient identities; and the creation of prescriber reference files. The prescriber reference files are then sold, licensed or transferred by the Petitioners to individuals and/or entities, including without limitation pharmaceutical survey researchers, pharmaceutical companies, and certain not-for-profit entities or groups, including without limitation educational institutions, public interest groups, and law enforcement agencies. The purchasers of that data use the information to better understand individual, national and international prescribing behavior, so as to promote their respective for-profit or not-for-profit purposes.

While Amici acknowledge that the Petitioners (like all other businesses) should not and do not have an unlimited right to conduct their respective business activities, the Petitioners' subject business activities now stand to be, but should not be, completely terminated as a result of, or radically restricted by, legislative efforts to limit the use of prescriber-identifiable information by one class of recipients or end-users of such information – the pharmaceutical manufacturers in the “detailing” and other direct marketing operations described below. The Petitioners are a source of reliable, legitimate and truthful information that has many uses, as discussed herein, other than pharmaceutical detailing or direct marketing of pharmaceutical products performed by those end-users who are the target of the Prescription Information Law, and thus termination of the

Petitioners' business lines is unfair, unnecessary, and draconian toward the Petitioners.

This unfair and unnecessary legislative approach has been followed by two states (i.e. Maine and Vermont) that have enacted, and numerous other state legislatures currently considering, legislation similar to the Prescription Information Law. The Petitioners have legally challenged both the Vermont and Maine statutes; the Vermont statute is currently under judicial review and the Maine statute has been struck down. This Court's ruling will determine whether New Hampshire, Maine and Vermont and the other state legislatures considering legislation similar to the Prescription Information Law will be allowed to terminate the Petitioners' subject business activities, not based on otherwise harmful, illegal, unethical or improper conduct on the part of the Petitioners, but rather for a particular use of Petitioners' products – pharmaceutical detailing and direct marketing to physicians – by certain of their clients. The result is and would be unfair, unnecessary and overbroad.

II. The Prescription Information Law and the First Circuit's Ruling Fail to Consider the Varied Uses of Prescriber-Identifiable Information and the Varied Businesses and Industries Using and Relying on Prescriber-Identifiable Information, thus Wrongly Depriving those Users of those Uses.

The First Circuit's analysis of the value of the Petitioners' products and services, and particularly the prescriber-identifiable information, is both inconsistent and incomplete. The First Circuit acknowledges that the vast amount of information collected by the Petitioners has considerable utility for non-profit entities such as educational institutions, public interest groups, and law enforcement agencies. *IMS Health, Inc.* at 46. Nonetheless, later in the First Circuit's opinion, the majority states that "the challenged portions of the statute [the Prescription Information Law] principally regulate conduct and to the extent that the challenged portions impinge at all upon speech, that speech is of scant societal value." *Id.* at 52. The First Circuit's reasoning appears to place a higher or lower value on the Petitioners' products and services depending upon the nature and business of a customer's use thereof.

The First Circuit's narrow focus on pharmaceutical detailing prevented the majority from considering and valuing the varied uses and benefits of prescriber-identifiable information and the related products and services of the Petitioners. The First

Circuit, like the New Hampshire legislature, appears to focus its analysis on the assumed unpopularity of a certain group of end-users of the prescription reference files (i.e. pharmaceutical detailers), and the uses of the prescription reference files by such end-users (i.e. pharmaceutical detailing and direct marketing of prescription drugs). The First Circuit's opinion on the "true nature" of the Petitioners' motivations or concerns with regard to the Prescription Information Law, and the benefits of prescriber-identifiable information, fails to fully appreciate and acknowledge the societal importance of prescriber-identifiable information and the many uses of, and the many businesses and industries using and relying on, such information.

Prescriber-identifiable information has substantial value to the general public and the pharmaceutical industry well beyond pharmaceutical detailing or direct marketing of prescription drugs. The prescriber-identifiable information and the related products and services of the Petitioners are used by pharmaceutical and medical device manufacturers and others to evaluate, improve and develop pharmaceutical products and medical devices; to evaluate and identify trends and risks in the options for the treatment and care of the general public; to evaluate, improve and develop best practices for the pharmaceutical, medical and health care industries; to evaluate, improve and develop truthful communications regarding treatment options, trends, and best practice; and to address global health care issues.

For example, Amici and their respective membership and the pharmaceutical survey research industry of which Amici and their respective members are a part, utilize and rely on the prescriber-identifiable information and the related products and services of the Petitioners in conducting their research, including without limitation conducting surveys with identified physicians concerning various treatment and care options, best practices and trends; and concerning pharmaceutical products and medical devices utilized within a physician's practice. For example, in performing pharmaceutical survey research for a pharmaceutical or medical device manufacturer, the pharmaceutical survey researchers will often contact physicians from a list of physicians that may be provided by the manufacturer of the drug or device. The physician list and contact information are usually obtained by the manufacturer from third party data providers including the Petitioners. Pharmaceutical survey researchers do not perform any pharmaceutical detailing or direct advertising, marketing, or promotion of a manufacturer's products or devices; indeed the ethical codes of Amici and other marketing research trade organizations expressly prohibit the researchers from (a) marketing, selling or promoting products and services to the physicians and other data subjects and (b) identifying the surveyed physicians and other data subjects to the researchers' manufacturer clients; Amici's members in good standing are expected to zealously adhere to those prohibitions; instead the researchers seek solely the opinions, experiences and ideas of physicians

related to the subject matter of the survey. As noted above, pharmaceutical survey research and pharmaceutical marketing research themselves – the businesses of Amici – are benign, socially productive endeavors that heavily use the Petitioners' data and similar data. Depriving these various users of such data would unnecessarily, unfairly and wrongly injure their businesses and deprive the public of their valued services.

In sum, the First Circuit failed to consider the varied uses of prescriber-identifiable information that have a direct, beneficial and significant impact on the pharmaceutical, medical and health care industries and on the advancements and developments in health-care, which benefits and impact will be severely restricted, if not completely lost, if this Court fails to reverse the First Circuit's ruling.

III. The First Circuit's Ruling Establishes Precedents that Would Permit State and Federal Governments to Restrict and/or Censor Other Reliable, Legitimate and Truthful Information Subject to a Significantly Reduced Level of Judicial Scrutiny.

Other parties to this matter have extensively pleaded the relationship between the right to free speech under the First Amendment to the Constitution and legitimate restraints on commercial activities. Amici will not reiterate all of those arguments, but instead will focus on a particular aspect of them.

The First Circuit's classification of the collection, aggregation and sale of reliable, legitimate and truthful information as "conduct" instead of "speech" could drastically reduce the level of judicial scrutiny required to uphold any governmental regulation prohibiting or restricting the use of such information. As a result, the Prescription Information Law and other "conduct" based laws might be viewed by some legislatures and courts as not falling within the scope of First Amendment protection and the intermediate level of scrutiny, as set forth in *Central Hudson Gas & Electric Corporation v. Public Services Comm'n of New York*, 447 U.S. 557, 566 (1980). Instead such "conduct" based laws might be viewed as an "economic regulation", thus subject to the lowest level of judicial scrutiny, the rational basis test. *IMS Health, Inc.* at 54. Under the rational basis test, a governmental regulation would be upheld if it is reasonably related to any legitimate government interest. The governmental regulation would be afforded a presumption of validity, absent a showing that negates every conceivable basis supporting such governmental regulation. *Federal Communications Commission and the United States v. Beach Communications, et al.*, 508 U.S. 307, 313-314 (1993) (citing *Lyng v. Automobile Workers*, 485 U.S. 360, 370 (1988) and *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973)).

The First Circuit's ruling thus could enable state and Federal governments to severely restrict, and censor, the use, transfer, disclosure and sale of other types of reliable, legitimate and truthful information

with little judicial scrutiny. State and Federal Governments could be able to capriciously restrict and censor information and data transactions, exchanges, transfers or uses that are unpopular but not harmful, illegal, unethical, or immoral.

The end result of unchecked governmental regulation on reliable, legitimate and truthful information would be devastating for Amici and its membership and any other business or industry relying on the availability of reliable, truthful and legitimate information in the performance of its business or activities. The unavailability of such information would severely limit the Amici's and their respective members' and such other businesses' and industries' ability to serve not only their direct clients, but also their indirect clients, the general public.



CONCLUSION

For the above stated reasons, Amici Curiae respectfully request that this Court grant the Petitioners' writ of certiorari and reverse the First Circuit's ruling and invalidate the Prescription Information Law.

Respectfully submitted,

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APPENDIX A

App. 1

CASRO – Who We Are – What We Do

Founded in 1975, the Council of American Survey Research Organizations (CASRO) represents over 300 companies and research operations in the United States and abroad.

CASRO is the “Voice and Values” of the survey research industry.

- We promote a rigorous code of conduct that enhances the image of survey research and protects the public’s rights and privacy
- We advocate our industry’s effective self-regulation when legislators propose bills that threaten legitimate survey research
- We champion legitimate research companies and marginalize disreputable research “pretenders” who threaten to tarnish the industry’s reputation and alienate respondents

CASRO requires members to adhere to the CASRO Code of Standards and Ethics for Survey Research, a tough, internationally-cited set of standards, which has long been the benchmark for the industry.

CASRO provides its members with numerous benefits, including access invaluable industry data, and superb staff training and networking opportunities at workshops and conferences throughout the country.

App. 2

CASRO has achieved unique status among all North American associations by serving as an active representative on numerous global initiatives and as chief liaison with several leading international associations.

CASRO's "Research Career Development" initiative reaches out to colleges and universities with information and resources to attract the best and brightest students and to make the survey research profession a career of choice.

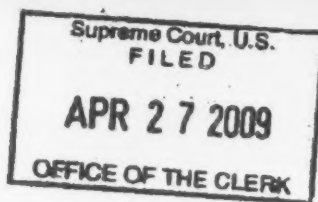
<http://www.casro.org/whatis.cfm>

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No. 08-1202



IN THE
Supreme Court of the United States

IMS HEALTH, INC. AND VERISPAN LLC,
Petitioners,

v.

KELLY M. AYOTTE, AS ATTORNEY GENERAL
OF THE STATE OF NEW HAMPSHIRE,
Respondent.

**On Petition for Writ of Certiorari
to the United States Court of Appeals
for the First Circuit**

**BRIEF AMICUS CURIAE
OF THE DATAMONITOR GROUP
IN SUPPORT OF PETITIONERS**

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IN THE
Supreme Court of the United States

No. 08-1202

IMS HEALTH, INC. AND VERISPAN LLC,
Petitioners,
v.

KELLY M. AYOTTE, AS ATTORNEY GENERAL
OF THE STATE OF NEW HAMPSHIRE,
Respondent.

On Petition for Writ of Certiorari
to the United States Court of Appeals
for the First Circuit

**BRIEF AMICUS CURIAE
OF THE DATAMONITOR GROUP
IN SUPPORT OF PETITIONERS**

**STATEMENT OF INTEREST
OF AMICUS CURIAE¹**

¹ Pursuant to Sup. Ct. R. 37.6, amicus notes that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amicus curiae, its members, or its counsel made a monetary contribution to its preparation or submission. All parties were notified of this amicus brief pursuant to Rule

The Datamonitor Group ("Datamonitor") is one of the world's leading providers of global business information. Datamonitor analysts collect and examine raw data gathered from a worldwide network of sources, applying extensive industry experience to assess and advise on market trends and conditions. Datamonitor's thousands of customers, which include Fortune 100 businesses and financial services organizations across the automotive, consumer markets, energy and utilities, financial services, logistics, pharmaceutical and healthcare, retail, technology, and telecommunication areas, rely on Datamonitor's reports to make informed business decisions. Datamonitor also provides its analyses to libraries and academic centers across the globe.

All of Datamonitor's divisions rely extensively on the collection and analysis of data obtained from a variety of sources. Most pertinently here, approximately eighty percent of the business of Datamonitor's Pharmaceutical and Healthcare division involves synthesizing "raw" mined data—including data provided by Petitioner IMS Health, Inc.²—with information from other sources to develop reports on market conditions, which are then broadly disseminated to pharmaceutical and other healthcare companies. The Pharmaceutical and Healthcare division is Datamonitor's largest, serving

37.2(a). The parties have consented to the filing of this brief through consent letters filed with the Clerk's Office.

² IMS Health obtains raw data about prescriptions, groups them by prescriber, and cross-references each prescribing physician's history with physician-specific information available through the American Medical Association. Pet. App. 5.

over 450 clients, including twenty-four of the thirty largest innovator pharmaceutical companies and many generic pharmaceutical manufacturers.

Datamonitor has a substantial interest in this case. If allowed to stand, the First Circuit's erroneous decision would render Datamonitor unable to obtain the raw pharmaceutical data critical to the development of its analyses of the market for prescription drugs in New Hampshire—not to mention any other state in the First Circuit now emboldened to pass a law like New Hampshire's.³ That prohibition would in turn make Datamonitor's analyses less useful for its customers—and thereby reduce the value of its products—with attendant financial harm to Datamonitor. Further, the First Circuit's holding that the transmittal of data that has been gathered, analyzed and repackaged (sometimes called "data mining") is not protected speech has implications across *all* of Datamonitor's businesses; for under the First Circuit's rationale, a state may lawfully prohibit the mining of data involving any industry. The petition thus presents an issue of exceptional importance to Datamonitor and to the industries that rely on its services to make informed, cost-effective business decisions. The First Circuit's decision warrants this Court's review.

³ Indeed, Maine passed a law like New Hampshire's before the district court decision below. That statute was invalidated in *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d. 153 (D. Me. 2008) prior to the First Circuit's decision here. Vermont also passed such a law, which was recently upheld. *IMS Health, Inc. v. Sorrell*, No. 1:07-CV-188 (D. Vt. Apr. 23, 2009). That court nonetheless disagreed with the First Circuit and held that prescriber information data is speech. Slip Op. at 13-14.

SUMMARY OF ARGUMENT

The free exchange of commercial information has been a key feature of American culture as long as there has been an America. See *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 495 (1996). New Hampshire's Prescription Information Law, however, makes it a crime for a pharmacy, insurer, or "similar entity" to "transfer" or "use" prescription data for the purpose of "any activity that could be used to influence sales or market share of a pharmaceutical product." N.H. Rev. Stat. § 318:47-f. The First Circuit upheld the statute against petitioners' First Amendment challenge, holding that the dissemination of information developed through the collection and analysis of raw data is not speech, but merely unprotected conduct. Pet. App. 26.

The First Circuit's holding should be reviewed and reversed, for it conflicts with multiple decisions from this Court and other circuit courts of appeal. This Court has held repeatedly that even the transmittal of *unprocessed* information is First Amendment speech. And it is similarly commonplace that the dissemination of *processed*—or, as referred to here, "mined"—information is the very essence of protected speech. Consider, for example, news organizations; they gather, analyze, and report data to inform, influence public opinion, and create sales every day.

But the First Circuit ignored all this, instead focusing on the actions of the *recipient* of the mined data—in this case, pharmaceutical sales representatives ("detailers") who use the data to market pharmaceuticals to physicians. But the speech here falls well outside the narrow category

that may be restricted because it may incite an unwelcome action or reaction on the part of the recipient. This is quite plainly not a case where a state seeks to regulate fraud or to prevent incitement to violence. Indeed, detailer speech is already regulated by federal statute, which prohibits false medical advertisements, and New Hampshire has never contended that the Prescription Information Law is necessary to curb such illegal activity. Legitimate speech—that of petitioners, Datamonitor, and other companies engaged in data mining—cannot be restricted when the listener then uses the content to engage in *more* legitimate speech.

If allowed to stand, the First Circuit's ruling will make it harder for businesses to obtain the information and analysis on which they rely to make informed, cost-effective decisions every day. Further, companies that mine and analyze data, like Datamonitor, provide this information to research institutions, universities, non-profits, and other organizations which would otherwise be unable to access the data. The importance of data mining is especially pronounced in the healthcare field; pharmaceutical companies make enormous research and development expenditures based on disease and market models derived from mined data, and academics and non-profits rely on such data to do work that benefits society in a variety of ways, including researching the spread of new diseases. And the First Circuit's rationale, of course, is not limited merely to the vast healthcare field; it will be invoked to broadly limit the use of mined data in other sectors of the economy. The First Circuit's decision thus undermines the fundamental exchange

of truthful information that is at the root of a free market system. This Court should grant certiorari.

ARGUMENT

I. THE FIRST CIRCUIT'S DECISION DIRECTLY CONFLICTS WITH DECISIONS OF THIS COURT AND ITS SISTER CIRCUITS.

The First Circuit readily acknowledged that New Hampshire's Prescription Information Law would "restrict the ability of data miners to aggregate, compile, and transfer information." Pet. App. 23-24. And the First Circuit recognized "that pure informational data can qualify for First Amendment protection." *Id.* 19. But the court nonetheless dismissed petitioners' claims that the transfer of this aggregated data constituted speech: According to the First Circuit, the aggregated information was a mere "commodity" like "beef jerky." *Id.* 23.

That holding conflicts with multiple decisions of this Court, as petitioners have thoroughly explained *See* Pet. 12-24. Petitioners' act of aggregating, compiling, and transferring information, after all, is fundamentally the same as the acts of gathering information, editing and analyzing it, and reporting it done each day by myriad news organizations around the country and the world. Such activity is at the very heart of the First Amendment's protections. *See Near v. Minnesota*, 283 U.S. 697, 707 (1931).

Contrary to the First Circuit's flip characterization of mined data as akin to a processed food, Pet. App. 23, moreover, data mining is a sophisticated exercise that involves synthesizing data and performing

statistical analyses to discover meaningful patterns that in turn can be used to predict future trends and behavior. Jeffrey W. Seifert, Congressional Research Serv., *Data Mining: An Overview* 1 (2004); Paul Decoff, *The Bottom Line on Data Mining*, 15 Mortgage Technology Magazine 1 (2008). After the data is analyzed, companies like petitioners and Datamonitor convey their findings and conclusions to their customers, sometimes through reports and sometimes by providing particular “slices” of the data. The ultimate product—the speech at issue here—thus necessarily reflects considered judgments as to what the data means, which data is significant, and how it should be interpreted and conveyed to customers. A data miner’s expert analysis and opinion are thus imbedded in the very transmittal of data; and it is that “product”—that speech—that clients pay for, and rely on, in making proactive and informed business decisions. See O. Folorunso & A. O. Ogunde, *Data Mining as a Technique for Knowledge Management in Business Process Redesign*, 13 Information Management and Computer Security 2 (2007). And a seller marketing to a buyer—here, a data miner marketing to a detailer—is classic commercial speech. 44 *Liquormart*, 517 U.S. at 496; see also *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976). The First Circuit’s characterization of that speech as unprotected “conduct” is in deep tension with this Court’s precedents and those of other circuits. See Pet. 12-20.⁴

⁴ As noted above, although the United States District Court for the District of Vermont recently upheld a law similar to New Hampshire’s, it nonetheless disagreed with the First

The First Circuit also contravened settled Supreme Court precedent by focusing not on the *act* of speech that the New Hampshire law purports to prohibit—petitioners’ transfer of prescriber-identifiable information—but instead on the ultimate end use of that information by pharmaceutical company sales representatives. According to the First Circuit, the rights of data mining companies are not implicated by the Prescription Information Law because data mining companies may still gather, analyze, publish and sell information “to whomever they choose so long as that person does not use the information for detailing.” Pet. App. 24 (emphasis in original). But a listener’s later actions (here, those of the sales representatives) implicate the rights of the speaker (here, petitioners) only in very limited circumstances—such as, for example, where the speaker’s statement is “directed to inciting or producing imminent lawless action and is likely to incite or produce such action.” See *Brandenburg v. Ohio*, 395 U.S. 444, 447 (1969) (per curiam). Such speech can be regulated because it carries a great and inherent risk of “substantive evils” that overcomes its First Amendment value. *Schenck v. United States*, 249 U.S. 47, 52 (1919). See also, e.g., *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 374–375 (2002) (speech restrictions permissible if speech is false); *Ohralik v. Ohio State Bar Ass’n.*, 436 U.S. 447, 465–466 (1978) (speech may be permissibly restricted when the danger of coercion was so high that a prophylactic measure was necessary to protect the consumer).

Circuit and held that prescriber information data is speech. *IMS Health Inc. v. Sorrell*, No. 1:07-CV-188 (D. Vt. Apr. 23, 2009), Slip Op. at 13-14.

This is, of course, not a case that resembles *Brandenburg* or *Ohralik* or anything remotely like those precedents' particulars. New Hampshire has never argued that petitioners' transfer of prescriber-identifiable data might incite "lawless action" by detailers. And New Hampshire has never contended that the statute was designed to combat factually inaccurate statements; after all, federal law already prohibits false medical advertisements. 21 C.F.R. § 202.1. Likewise, there is no danger of undue coercion (another basis for restricting speech based on the action or reaction of the listener); far from being "unsophisticated, injured, or distressed lay" people, *Ohralik*, 436 U.S. at 465, physicians are highly-trained professionals who make prescription decisions every day. See also *Edenfield v. Fane*, 507 U.S. 761, 775–776 (1993) (rejecting claim that a ban on solicitation between an accountant and a lay person survived First Amendment scrutiny because the ban was prophylactic in light of accountants' specialized expertise).

If allowed to stand, the First Circuit's holding presents the very real possibility that speech relying on the aggregation of data will be broadly denied First Amendment protection—not just under new Hampshire's prescription-information statute, but more generally. And the First Circuit's wrongheaded, *recipient-focused* analysis will relatedly encourage state legislatures to vastly expand the once-narrow category of speech that can be regulated based on the actions of the listener. Both of these results constitute dramatic departures from this Court's precedents. The Court should grant certiorari.

II. THE ISSUE PRESENTED IS OF NATIONAL SIGNIFICANCE.

A. Data Mining Firms Add Substantial Value To Raw Statistical Data.

Data mining firms like Datamonitor do far more than simply aggregate raw data; they interpret data and provide prescriptive advice to clients. Datamonitor analysts are skilled professionals with significant industry knowledge in their relevant fields; they include, for example, physicians, university researchers and professors, high-profile scientists and industry executives.

Datamonitor's process consists of several steps. Datamonitor analysts often begin by locating and sorting large volumes of data, often of a variety of types. Thus, in (for example) the healthcare industry, Datamonitor analysts commence their work with large volumes of data received from database warehouses, such as sales and promotional data from petitioner IMS Health, pharmaceutical data from Thomson, market data from MedTRACK, research and development data from Iddb3, and epidemiological and patient data sets provided by organizations such as the World Health Organization, IMPAC's National Oncology Database, and GLOBOCAN. Datamonitor also collects its own research, directly or through market research partners, from physicians and other healthcare stakeholders. Datamonitor also receives health and regulatory data from public databases including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency. Analysts also consult a variety of other sources, including reviewing publications in the field, interviewing leading figures

in the applicable field, and analyzing company-reported sales, broker's reports and news feeds. Based on their review of all this information, and taking into account their experience in the relevant markets, analysts provide Datamonitor's clients with detailed strategic analyses. Datamonitor's efforts provide great value to its customers, researchers and academics. Far from a "commodity" like "beef jerky," as the First Circuit held, *cf. Pet. App. 23*, Datamonitor's work quite plainly produces speech.

B. Data Mining Is An Essential Tool For Companies In Nearly Every Industry.

Organizations big and small, for-profit and not-for-profit alike, make critical business decisions every day—what to manufacture, or what to stock, or how much of what product to order, or where to spend critical research and development resources. The choices those organizations make often (and sometimes by design) are felt well beyond the organization itself, affecting the consumers who want or need the product, or the employees who make it, or the intermediaries who distribute it, or sometimes even more broadly the regions in which the organizations are located.

To make their decisions in an informed and cost-effective way, companies reasonably seek access to all relevant information. See *Data Mining in the Meltdown: the Last, Best Hope?*, CFO Magazine, Feb. 12, 2009, at 1. Reliable statistical data—and expert analyses based on that data—are especially useful tools for decision-making. Datamonitor's own customer list of over 6,000 leading corporations demonstrates the value that successful organizations in a wide variety of industries place on data mining.

See Datamonitor website, <http://www.informa.com/brands/datamonitor> (last visited April 23, 2009). Datamonitor's customers—including manufacturers, financial services companies, and many other industries—rely on Datamonitor's services to address complex strategic issues, predict future trends, and respond effectively to the market.

For instance, many pharmaceutical companies depend on Datamonitor to analyze drug launch strategies in the United States and major European markets. Datamonitor analysts sort through databases, examine market trends, regulatory impacts, patient empowerment and disease management reports, and identify strategies to increase the market "voice" of each product. These analyses give Datamonitor's pharmaceutical clients a basis for making informed and cost-effective decisions about where to focus their resources in terms of products, geographic markets, design and other investments.

Similarly, in the automotive industry, Datamonitor analyzes relationships and patterns in the market to predict how it will evolve in the future. Datamonitor provides detailed coverage of the size and segmentation of the markets, including specific breakdown by country, product family and retail channel, identifies where market opportunities exist, and offers recommendations on how to maximize the returns for their businesses. Car manufacturers can use this information to gain a better understanding of the market and make informed decisions before investing in new technology or expanding into a new region. This in turn helps manufacturers avoid the

high costs associated with investing large sums of money in unprofitable markets.

Datamonitor's analyses are also used in academia. Datamonitor distributes data and analyses to universities and public libraries. University researchers, professors, specialists and Nobel Prize winning scientists are part of Datamonitor's Lifescience Analytics Research Board. The insights provided by these researchers, together with Datamonitor's proprietary analyses, helps other scientists and academics develop ground-breaking technology and improve therapeutic research in areas of significant unmet medical need, such as prostate cancer, renal cell carcinoma, multiple myeloma and malignant melanoma.

All of these (and many more) myriad uses, and users, of "mined" statistical information confirm the importance of this issue in the national economy. See *Bigelow v. Virginia*, 421 U.S. 809, 825-826 (1975) (commercial speech has value in the marketplace of ideas). The "free flow of commercial information is indispensable" in a free enterprise economy, where allocation of resources is made predominantly through numerous private economic decisions. *Virginia State Bd. of Pharmacy*, 425 U.S. at 765. It is critical that those economic decisions be well-considered, and before a decision may be well-considered it must be sufficiently well-informed. Companies depend on data mining for the reliable business data necessary to make those informed and efficient decisions that are critical to the success of their businesses—and to the economy more generally. The First Circuit's erroneous characterization of this vital commercial speech as valueless "conduct" denies businesses some of the

information they need to carry out their functions effectively and well, places those companies at a competitive disadvantage, and impedes efficient use of their capital. The implications are just that stark; and the First Circuit's decision should be taken up, reviewed, and reversed before its analysis catches any further hold.

CONCLUSION

For the foregoing reasons, and those in the petition, the petition should be granted.

Respectfully submitted,

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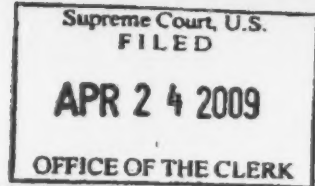
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No. 08-1202



In the
Supreme Court of the United States

IMS HEALTH, INC. AND VERISPAN LLC,

Petitioners,

v.

**KELLY M. AYOTTE, AS ATTORNEY GENERAL
OF THE STATE OF NEW HAMPSHIRE,**

Respondent.

On Petition for a Writ of Certiorari to the United
States Court of Appeals for the First Circuit

**BRIEF OF AMICI CURIAE NEW ENGLAND LEGAL
FOUNDATION, ASSOCIATED INDUSTRIES OF
MASSACHUSETTS, ASSOCIATED INDUSTRIES OF VERMONT,
MAINE MERCHANTS ASSOCIATION, AND AMERICAN
LEGISLATIVE EXCHANGE COUNCIL,
IN SUPPORT OF PETITIONERS**

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April 24, 2009

QUESTION PRESENTED

Amici curiae adopt the Questions Presented as stated by Petitioners. This amicus brief focuses on the first question as stated by Petitioners:

To what extent does the First Amendment protect the acquisition, analysis, and publication of accurate factual information that is used by third parties for a commercial purpose?

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INTEREST OF AMICI CURIAE

Amici curiae New England Legal Foundation ("NELF"), Associated Industries of Massachusetts ("AIM"), Associated Industries of Vermont ("AIV"), Maine Merchants Association ("MMA"), and American Legislative Exchange Council ("ALEC") seek to share their views concerning the need for this Court to clarify the fact and extent of the protection afforded by the First Amendment of the U.S. Constitution to the sale of information for commercial use.¹

NELF is a nonprofit, nonpartisan, public interest law firm, incorporated in Massachusetts in 1977 and headquartered in Boston. Its membership consists of corporations, law firms, individuals, and others who believe in NELF's mission of promoting balanced economic growth in New England, protecting the free enterprise system, and defending economic rights. NELF's more than 130 members and supporters include a cross-section of large and small businesses from all parts of New England and the United States.

AIM is a 90-year-old nonprofit association with over 7,000 employer members doing business in the Commonwealth of Massachusetts. AIM's mission is to promote the well-being of its members and their employees,

¹ Pursuant to Supreme Court Rule 37.6, counsel for amici state that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund its preparation or submission. Moreover, no person other than amici curiae, their members, or their counsel made a monetary contribution to the brief's preparation or submission. Pursuant to Supreme Court Rule 37.2(a), counsel for amici state that counsel of record for all parties received notice at least ten days prior to the due date of amici's intention to file this brief. The parties have consented to its filing.

and the prosperity of the Commonwealth, by: improving the state's economic climate; proactively advocating fair and equitable public policy; and providing relevant and reliable information and excellent services.

Founded in 1920, AIV serves as an advocate for Vermont's industrial and business communities in the formulation of public policy that protects and enhances Vermont's private enterprise economy. AIV provides legislative and regulatory advocacy and representation at the state and federal levels and its membership runs the full range of the manufacturing, technology, and natural resource sectors, with companies of every size and from every part of the state.

MMA is a nonprofit organization with over 400 members and represents the interests of the retail merchant industry before elected Maine officials. MMA's lobbying and issue education efforts are designed to ensure sound policy decisions on issues that directly affect Maine businesses, including wage and hour issues, workers' compensation and healthcare costs, employee benefits, and taxes.

ALEC is a nonprofit organization dedicated to the advancement of the Jeffersonian principles of free markets, limited government, federalism, and individual liberty, through a nonpartisan public-private partnership of America's state legislators, members of the private sector, the federal government, and the general public. More than 25% of all state legislators belong to ALEC, along with more than 300 corporate and private foundation members.

NELF, AIM, and ALEC have regularly appeared as amici curiae in cases raising issues of general significance to their members.² This is such a case, and NELF, AIM, AIV, MMA, and ALEC (hereafter, "Amici") believe that this brief provides an additional perspective which may aid the Court in determining whether to grant the Petition For A Writ of Certiorari ("Pet.").

SUMMARY OF ARGUMENT

The First Circuit decision that has occasioned this petition is in conflict with the decisions of this Court providing that the transfer of information constitutes speech entitled to First Amendment protection. The First Circuit's decision is likewise in conflict with the decisions of this Court applying the commercial speech doctrine, although language in certain of the Court's opinions has engendered

² See, e.g., *Ysursa v. Pocatello Educ. Ass'n*, __U.S.__, 129 S. Ct. 1093 (2009); *District of Columbia v. Heller*, __U.S.__, 128 S. Ct. 2783 (2008); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007); *Davenport v. Wash. Educ. Ass'n*, 551 U.S. 177 (2007); *Watters v. Wachovia Bank, N.A.*, 550 U.S. 1 (2007); *League of United Latin Am. Citizens v. Perry*, 548 U.S. 399 (2006); *Rapanos v. United States*, 547 U.S. 715 (2006); *S.D. Warren Co. v. Maine Bd. of Envtl. Prot.*, 547 U.S. 370 (2006); *Kelo v. City of New London*, 545 U.S. 469 (2005); *San Remo Hotel, L.P. v. City of San Francisco*, 545 U.S. 323 (2005); *Exxon Mobil Corp. v. Saudi Basic Indus. Corp.*, 544 U.S. 280 (2005); *Comm'r v. Banks*, 543 U.S. 426 (2005); *Commonwealth v. Fremont Inv. & Loan*, 452 Mass. 73 (2008); *Saab v. Massachusetts CVS Pharmacy, LLC*, 452 Mass. 564 (2008); *Thurdin v. SEI Boston, LLC*, 452 Mass. 436 (2008); *Salvas v. Wal-Mart Stores, Inc.*, 452 Mass. 337 (2008); *Iannacchino v. Ford Motor Co.*, 451 Mass. 623 (2008); *Moelis v. Berkshire Life Ins. Co.*, 451 Mass. 483 (2008).

considerable confusion regarding the proper contours of that doctrine, as evidenced by conflicting decisions among the circuits and even within the First Circuit.

The Court should issue a writ of certiorari to resolve this doctrinal confusion in favor of the “proposes a commercial transaction” definition of commercial speech. The Court would thereby prevent the substantial harm to social and economic interests that could result if, as the First Circuit has decided, every sale of information for a commercial purpose deemed by the judiciary to have minimal societal value may on that basis be denied First Amendment protection or afforded the lower level of protection from government regulation that attaches to commercial speech.

ARGUMENT

I. Certiorari is warranted because the First Circuit’s decision conflicts with this Court’s decisions holding that the transfer of information constitutes speech protected by the First Amendment.

As District Judge Barbadoro noted when he enjoined the statute’s enforcement, the New Hampshire Prescription Information Law, 2006 N.H. Laws § 328, *codified at* N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006), “bars pharmacies, insurance companies, and similar entities from transferring or using prescriber-identifiable data for certain commercial purposes.” *IMS Health Incorporated v. Ayotte*, 490 F. Supp. 2d 163, 165 (D.N.H. 2007), *rev’d*, 550 F.3d 42 (1st Cir. 2008). Judge Barbadoro further recognized,

as the First Circuit apparently does not, that this constitutes a direct restriction on the "transmission of truthful information," and therefore on "speech." *Id.* at 175. See *Bartnicki v. Vopper*, 532 U.S. 514, 526-27 (2001) (a "prohibition against disclosures is fairly characterized as a regulation of pure speech"); *Stanley v. Georgia*, 394 U.S. 557, 564 (1969) ("It is now well established that the Constitution protects the right to receive information This right . . . is fundamental to our free society.").³

The First Circuit appears to have been disturbed by the fact that, in this instance, the information to be transferred has monetary value and is therefore bought and sold like a "commodity." App. at 23. However, the transfer or dissemination of information does not lose its status as speech under the First Amendment merely because money passes hands. See, e.g., *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761 (1976)

³ As the First Circuit's opinion does recognize, the First Amendment applies to even "pure informational data." Appendix to Petition for a Writ of Certiorari ("App.") at 19. It is, in fact, because product advertising conveys factual information that even it has First Amendment protection. See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 563 (1980) ("The First Amendment's concern for commercial speech is based on the informational function of advertising."); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976) ("Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reason, and at what price [T]he free flow of commercial information is indispensable."); *Wine and Spirits Retailers, Inc. v. R.I.*, 481 F.3d 1, 6 (1st Cir. 2007) (acknowledging that the "dissemination of information about . . . prices and products to other retail stores and to the public at large" constitutes "speech" for First Amendment purposes).

(speech "carried in a form that is 'sold' for profit" does not lose protection); *Smith v. California*, 361 U.S. 147, 150 (1959) ("It is of course no matter that the dissemination takes place under commercial auspices."); *Murdock v. Pennsylvania*, 319 U.S. 105, 111 (1943) ("It should be remembered that the pamphlets of Thomas Paine were not distributed free of charge.").

Nor is the First Circuit correct that the Prescription Information Law principally regulates conduct rather than speech. App. at 22-26. Again, the statute directly regulates the disclosure of truthful information by pharmacies and others to the petitioners and "[i]f the acts of 'disclosing' and 'publishing' information do not constitute speech, it is hard to imagine what does" *Bartnicki*, 532 U.S. at 527; see also *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 457 (1978) (distinguishing the regulation of a "business transaction [face-to-face solicitation of clients by lawyers] in which speech is an essential but subordinate component" from the direct regulation of speech).

Finally, the First Circuit is incorrect to the extent it is suggesting that a complete ban on any transfer of this information would be necessary to trigger First Amendment protection. App. at 23-24 ("The plaintiffs may still gather and analyze [prescriber-identifiable information]; and may publish, transfer, and sell this information to whomever they choose so long as that person does not use the information for detailing.") The First Amendment proscribes laws "abridging," or restricting, free speech, as well as those that ban speech. U.S. Const. amend. I; see also *Florida Bar v.*

Went for It, Inc., 515 U.S. 618, 622 (1995) (“[T]he First Amendment guards against government restriction of speech in most contexts . . .”).

The fundamental basis for the First Circuit’s approach in this case appears to be an erroneous belief that courts are free to act on their own judgments about the value to society of particular information. Amici do not begin to agree with the First Circuit’s conclusion that the speech at stake here is “of scant societal value.” App. at 22. Even more importantly, however, Amici do not find in this Court’s First Amendment jurisprudence permission for either state legislatures or federal judges to ignore the First Amendment because they perceive the speech at issue to be lacking in value. See *Edenfield v. Fane*, 507 U.S. 761, 766 (1993) (“[T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented.”)

The implications of the First Circuit’s approach extend far beyond the specific context of pharmaceutical marketing at issue in this case. Amici’s members include representatives of a wide variety of industries, and Amici are deeply concerned that if information used to market drugs can be suppressed without regard to First Amendment protections, the same fate can befall information that other enterprises require to market their products and services or otherwise run their businesses.

This Court should issue a writ of certiorari to evaluate the First Circuit’s dangerous departure from the Court’s First Amendment precedent.

II. Certiorari is warranted because the First Circuit has decided an important question regarding the scope of the commercial speech doctrine under the First Amendment in a way that conflicts with this Court's actual application of that doctrine but derives from uncertainty created by the Court's opinions.

As District Judge Barbadoro's decision in this litigation again recognizes, the contours of "commercial speech" are not entirely clear from this Court's decisions. *Ayotte*, 490 F. Supp. 2d at 176. In its decision in *Central Hudson*, the Court appeared to define commercial speech as that which "proposes a commercial transaction," but also indicated that commercial speech is "related solely to the economic interests of the speaker and its audience." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 561-63 (1980). The Court's decision in *Board of Trustees of State University of New York v. Fox*, 492 U.S. 469 (1989), rendered after *Central Hudson*, very clearly employed the "proposes a commercial transaction" definition, describing it as "the test for identifying commercial speech." *Id.* at 473-74. This suggests that the language in *Central Hudson* regarding the speaker's and listener's economic interests was meant to be descriptive of speech that "proposes a commercial transaction," rather than an independent definition of commercial speech. *See United States v. United Foods, Inc.*, 533 U.S. 405, 409 (2001) (commercial speech is "usually defined as speech that does no more than propose a commercial transaction");

Commodity Futures Trading Comm'n v. Vartuli, 228 F.3d 94, 110 n.8 (2d Cir. 2000) (discussing ramifications of using the *Central Hudson* "description as a definition"). However, in *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 422 (1993), the Court interpreted *Central Hudson* as suggesting that there could be speech that does not propose a commercial transaction and yet qualifies as commercial speech because it is "related solely to the economic interests of the speaker and its audience."

As the petitioners explain, the uncertainty in the Court's decisions regarding the definition of "commercial speech" has led to conflicting decisions among the circuits. Pet. at 21-23. The First Circuit in this case has employed the broader "economic interests" concept as an actual definition of commercial speech, citing its prior decisions in *Pharmaceutical Care Management Ass'n v. Rowe*, 429 F.3d 294 (1st Cir. 2005) and *El Dia, Inc. v. Puerto Rico Department of Consumer Affairs*, 413 F.3d 110 (1st Cir. 2005). App. at 27-28. The Second Circuit, however, applies the "proposes a commercial transaction" definition. See *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 96-97 (2d Cir. 1998) (Bad Frog's label "serves to propose a commercial transaction" and communicates the source of the product such that it "suffices to invoke the protections for commercial speech . . ."); *N.Y. State Ass'n of Realtors, Inc. v. Shaffer*, 27 F.3d 834, 840-41 (2d Cir. 1994) (solicitation of homeowners by realtors seeking the right to sell residential property " 'is primarily aimed at proposing a commercial transaction' " and should therefore be considered commercial

speech). Since this contrary Second Circuit precedent will govern the pending challenge to Vermont's version of the Prescription Information Law,⁴ the conflict in circuit decisions on this fundamental question is manifest even in the limited arena of pending litigation over state statutes restricting the transfer and use of prescriber-identifiable data.

The confusion that reigns regarding the scope of the commercial speech designation is further evidenced by conflicting decisions from the First Circuit itself. Thus, while the *Pharmaceutical Care* and *El Dia* First Circuit decisions cited by that court in its opinion in this case apply the broader "economic interests" formulation, *see* discussion *supra* p. 9, other First Circuit decisions apply the "proposes a commercial transaction" test. *See Wine and Spirits Retailers, Inc. v. R.I.*, 418 F.3d 36, 49 (1st Cir. 2005) ("The provision of advertising and licensing services is not speech that proposes a commercial transaction and therefore does not constitute commercial speech." (citing *Fox*, 492 U.S. at 482, as indicating that the "proposal of a commercial transaction . . . 'is what defines commercial speech,' . . .")); *Wine and Spirits Retailers, Inc. v. R.I.*, 481 F.3d 1, 6 (1st Cir. 2007) (same).⁵ This conflict even within a single circuit

⁴ The Vermont case is *IMS Health v. Sorrell*, No. 1:07-cv-00188, consolidated with 1:08-cv-00220 (D. Vt. filed Aug. 29, 2007).

⁵ The fact that Circuit Judge Selya wrote the two *Wine and Spirits* decisions as well as the First Circuit's decision in this case compounds the confusion.

demonstrates the extent of the confusion generated by *Central Hudson* and its progeny.

Despite the confusion generated by the “economic interests” language in *Central Hudson*, this Court has never actually found speech to be “commercial speech” except where it involves direct or indirect advertising. See Eugene Volokh, *Freedom of Speech and Information Privacy: The Troubling Implications of a Right to Stop People From Speaking About You*, 52 Stan. L. Rev. 1049, 1082 (2000).⁶ In fact, the Court has struggled with applying the “commercial speech” label even in the advertising context. Thus, in *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66-67 (1983), the Court, after designating as commercial speech mailings of unsolicited advertisements for contraceptives that consisted primarily of price and quantity information, indicated that it was addressing a “closer question” in classifying as commercial speech what the Court subsequently described as “informational pamphlets that were concededly advertisements referring to a specific product”—i.e., advertising combined with other informational speech. *City of Cincinnati*, 507 U.S. at 422-23 (discussing *Bolger*).

The separate opinions of several justices in the case of *Nike, Inc. v. Kasky*, 539 U.S. 654 (2003), in which the Court dismissed a previously granted writ of certiorari as having been improvidently granted, are also instructive. A California citizen sued Nike for false advertising and unfair

⁶ Amici have conducted independent research on this question, and this appears to continue to be the case post-2000.

business practices based on a report and other publications (press releases, letters to newspaper editors, and letters to university presidents and athletic directors) by Nike denying allegations of poor working conditions at its facilities in foreign countries. The California Supreme Court found that “ ‘[b]ecause the messages in question were directed by a commercial speaker to a commercial audience, and because they made representations of fact about the speaker’s own business operations for the purpose of promoting sales of its products, . . . [the] messages are commercial speech.’ ” *Id.* at 657 (Stevens, J., concurring) (quoting *Kasky v. Nike, Inc.*, 27 Cal. 4th 939, 946 (2002)). Concurring in the Court’s reversal of its prior decision to hear the case, Justice Stevens (joined by Justices Ginsburg and Souter) characterized Nike’s speech as combining commercial speech, noncommercial speech, and public discourse, and indicated that the case therefore raised novel First Amendment issues better addressed on a fuller factual record. *Id.* at 663-64. Focusing on Nike’s “direct communications with customers and potential customers that were intended to generate sales—and possibly to maintain or enhance the market value of Nike’s stock,” the concurring justices raised the prospect of according even misstatements contained in that speech protection comparable to the “broad protection for misstatements about public figures that are not animated by malice,” because these communications with actual and potential customers “were part of an ongoing discussion and debate about important public issues” *Id.* at 664.

Similarly, Justice Breyer (joined by Justice O'Connor), dissenting from the Court's decision not to hear the *Nike* case, wrote that even the direct correspondence with university presidents and athletic directors who were actual and potential Nike customers was distinguishable from "purer forms of commercial speech, such as simple product advertisements," and should, given the circumstances presented as to "format, content, and regulatory context," be subjected to heightened scrutiny. *Id.* at 678-79 (Breyer, J., dissenting). Justice Breyer further opined that "it is likely, if not highly probable, that, if this Court were to reach the merits, it would hold that heightened scrutiny applies" *Id.* at 681.

In *Nike*, therefore, five justices (including four who remain on the Court) indicated at least an inclination to treat certain direct speech by a business to its customer base designed to encourage purchase of its products as deserving of heightened protection associated with noncommercial speech. Those justices would likely find such heightened protection even more appropriate here, where a statute restricts informational transfers that neither constitute nor are combined with direct or indirect product promotions.

In sum, while the Court has never expressly disavowed the *Central Hudson* "economic interests" phraseology, its later decisions demonstrate a clear reluctance to apply the "commercial speech" label except to speech that primarily entails advertising or marketing. Moreover, a frequently cited explanation for granting commercial speech lesser protection than other speech is the fact that it is

“‘linked inextricably’ with the commercial arrangement that it proposes, so the State’s interest in regulating the underlying transaction may give it a concomitant interest in the expression itself.” *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) (citation omitted); see also *Friedman v. Rogers*, 440 U.S. 1, 10 n.9 (1979). This justification for lesser First Amendment protection applies only to speech that directly proposes a commercial transaction, and not to other speech that relates solely to economic interests. Cf. *Bolger*, 463 U.S. at 65 (“In light of the greater potential for deception or confusion in the context of certain advertising messages, content-based restrictions on commercial speech may be permissible.”) (emphasis supplied) (citation omitted).

Both judges and commentators have noted significant concerns with reliance on the broader language of *Central Hudson* as a definition of commercial speech. The following discussion is illustrative:

The Court has at times suggested that the commercial speech category may also generally cover speech that is ‘related solely to the economic interests of the speaker and its audience,’ and some lower courts have accepted this definition. But this can’t be right. Consider . . . the newspaper that discusses business affairs, almost entirely in order to make money by helping its readers do well in business. Consider a product review written by its author because he wants to be paid, published by the newspaper because it wants to keep its paying

subscribers, and read by readers because they want to know how to best spend their money. Consider a union buying TV ads urging people to 'Buy American' because that's the best way of maintaining the viewers' (and the union members') standard of living.

. . . That [such commentary] has to do with the listeners' economic interests merely highlights its importance—for most people, economic well-being is more important than politics, art, social concerns, or often even religion, and speech on economic matters often has more effect on the nation than does most art or theology, or even much political debate.

Volokh, 52 Stan. L. Rev. at 1081-82 (footnotes omitted);⁷ *see*

⁷ Professor Volokh continues:

If communicating information about a person's bad credit record is mere 'commercial speech,' then communicating information about a business's bad service record should be too. Both, after all, involve speech on economic matters. Both involve speech that's primarily of economic interest to listeners. Both are motivated by the speaker's economic interest -- either a desire to get money from the buyer of the information, or a desire to get redress from the business. Either both are commercial speech or neither is.

In a free and competitive economy, people naturally want to talk about economic matters. Often their motives for such speech are largely economic: They want to learn how to make more money. They want to persuade people that some course of action is economically better. They

also Troy L. Booher, *Scrutinizing Commercial Speech*, 15 Geo. Mason U. Civ. Rts. L.J. 69, 70 (2004) ("[S]peakers are rarely motivated by a monolithic desire for profit and . . . it is difficult to determine when speech is sufficiently motivated by a desire for profit to warrant a different level of protection.").

Justice Stevens anticipated these problems in his concurring opinion in *Central Hudson*:

The Court first describes commercial speech as 'expression related solely to the economic interests of the speaker and its audience.' Although it is not entirely clear whether this definition uses the subject matter of the speech or the motivation of the speaker as the limiting factor, it seems clear to me that it encompasses speech that is entitled to the maximum protection afforded by the First Amendment. Neither a labor leader's exhortation to strike, nor an economist's dissertation on the money supply, should receive any lesser protection because the subject matter concerns only the

want to alert people to what they think are others' dishonest business practices. Giving the government an ill-defined but potentially very broad power to restrict such speech -- not just speech that proposes a commercial transaction between speaker and listener and thus directly implicates the risk of fraud -- risks exposing a great deal of speech to government policing.

Id. at 1087.

economic interests of the audience. Nor should the economic motivation of a speaker qualify his constitutional protection; even Shakespeare may have been motivated by the prospect of pecuniary reward. Thus, the Court's first definition of commercial speech is unquestionably too broad.

447 U.S. at 579-80 (Stevens, J., concurring) (citation omitted).

The transfer, whether by sale or otherwise, of prescriber-identifiable data or other factual information from one willing business to another obviously does not "propose a commercial transaction." "It doesn't advertise anything, or ask the receiving business to buy anything from the communicating business The recipient business does intend to use the information to more intelligently engage in commercial transactions, but that's equally true of businesspeople reading *Forbes*." Volokh, 52 *Stan. L. Rev.* at 1082-83 (footnotes omitted). And yet the First Circuit has concluded that such transfers, if they constitute speech at all, are entitled to only the lesser degree of protection from government regulation afforded commercial speech.

This Court should issue a writ of certiorari in this case so as to resolve the widespread confusion, evidenced by conflicting judicial decisions, concerning the definition of commercial speech and, for the reasons noted by both judges and commentators, limit its scope to speech that proposes a commercial transaction. Resolution of the question, and in this way, could not be more important because proper

application of the "commercial speech" label is necessary to "ensure that speech deserving of greater constitutional protection is not inadvertently suppressed." *Bolger*, 463 U.S. at 66.⁸

III. Certiorari is warranted because the First Circuit's approach could significantly impede the flow of information in our society.

It is well recognized that "scientific and technological advances facilitate the ability to both gather and disseminate information, increasing the demand for and uses of information" Barry P. McDonald, *The First Amendment and the Free Flow of Information: Towards A Realistic Right to Gather Information in the Information Age*, 65 Ohio St. L.J. 249, 262 (2004). Market forces provide the incentives and resources needed to meet this increased demand for information. See *Buckley v. Valeo*, 424 U.S. 1, 19 (1976) ("[V]irtually every means of communicating ideas in today's mass society requires the expenditure of money."); Solveig Singleton, *Privacy as Censorship: A Skeptical View of Proposals to Regulate Privacy in the Private Sector*, Cato Policy Analysis No. 295 (January 22, 1998), <http://www.cato.org/pubs/pas/pa-295.html> ("The formal

⁸ Indeed, it is unclear to Amici that there will be any compilation and transfer of prescriber-identifiable data at all, in order for it to serve noncommercial purposes such as healthcare research, if the Prescription Information Law and other statutes like it are upheld. To the extent these laws effectively restrict all transfers and uses of prescriber-identifiable data by eliminating the market incentives and resources that permit the aggregation and dissemination of the data, see discussion *infra* pp. 18-20, the statutes undeniably impinge on noncommercial speech.

mechanisms that businesses have developed to transfer information about consumers, borrowers, and other businesses serve valuable economic and social purposes formerly served by person-to-person informal information networks.”)

Just as speech “does not lose its First Amendment protection because money is spent to project it,” *City of Cincinnati*, 507 U.S. at 420, the mere fact that a business has disseminated information should not make that publication commercial speech. In our “information age,” sales and other voluntary transfers of data by and between businesses are fundamental to the efficient operation of the free enterprise system and often serve, as in this instance, societal needs as well as the interests of individual businesses. Thus, treating the sale of information for a commercial purpose as less deserving of First Amendment protection than other informational transfers can be expected to have serious, adverse ramifications for both economic and social interests served by the free flow of information in our society.

If, for example, the transfer of prescriber-identifiable data for a commercial purpose can be proscribed, the effect may be to circumscribe as well the compilation and transfer of prescriber-identifiable data for noncommercial purposes such as healthcare research. In addition, if pharmaceutical companies are unable to focus their marketing activities based on prescriber-identifiable data, those marketing efforts will be less efficient and more expensive. This could lead to higher prescription drug prices and associated higher health insurance costs for employers, including Amici’s many

members already struggling to meet their employees' healthcare needs.

In short, because market forces fuel the compilation and publication of most information in modern society, efforts to restrict the transfer and use of data for commercial purposes will likely have consequences far beyond that intended focus to the detriment of the public interest. It is therefore critical that direct, legislative restrictions on the sale of information for commercial purposes such as that contained in the Prescription Information Law not escape First Amendment scrutiny or be evaluated under the lesser standard of scrutiny applicable to commercial speech. This Court's attention to the matter could not be more important or timely.

CONCLUSION

For the reasons stated above, the Court should grant the Petition For A Writ of Certiorari of IMS Health, Inc. and Verispan LLC.

Respectfully submitted,

NEW ENGLAND LEGAL FOUNDATION,
ASSOCIATED INDUSTRIES OF
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INDUSTRIES OF VERMONT, MAINE
MERCHANTS ASSOCIATION, AND
AMERICAN LEGISLATIVE EXCHANGE
COUNCIL

By their attorneys,

A handwritten signature in dark ink, appearing to read "Jo Ann Shotwell Kaplan". The signature is fluid and cursive, with the first name "Jo" being particularly prominent.

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In the
Supreme Court of the United States

IMS HEALTH, INC., *et al.*,

Petitioners,

v.

KELLY A. AYOTTE, Attorney General
of New Hampshire,

Respondent.

On Petition for Writ of Certiorari
to the United States Court of Appeals
for the First Circuit

**BRIEF AMICUS CURIAE OF
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IN SUPPORT OF PETITIONERS**

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QUESTIONS PRESENTED

For decades, publishers have acquired doctors' prescribing histories and used the information to publish reports. Drug companies use that information to deliver information about new products to doctors. New Hampshire has made it a crime to transfer prescribing histories within the state to increase brand-name drug sales. The First Circuit held that the law does not implicate the First Amendment because it targets conduct and involves only speech with "scant societal value." Alternatively, it held that the First Amendment permits the government to "level the playing field" in communications with doctors, notwithstanding that the law in fact "may not accomplish very much."

The Questions Presented are:

1. To what extent does the First Amendment protect the acquisition, analysis, and publication of accurate factual information that is used by third parties for a commercial purpose?
2. Does the First Amendment permit such a prohibition when the government seeks to "level the playing field" by inhibiting truthful speech while simultaneously permitting the use of the identical information for communication of the state's preferred viewpoint?
3. Does the First Amendment permit such a prohibition when it is both grossly underinclusive (because it is so riddled with exceptions that it "may not accomplish very much") and overinclusive (because it inhibits even communication that the state acknowledges benefits public health)?

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INTEREST AND IDENTITY OF AMICUS CURIAE

Pacific Legal Foundation (PLF) respectfully submits this brief amicus curiae in support of the Petitioner.¹

PLF was founded more than 35 years ago and is widely recognized as the largest and most experienced nonprofit legal foundation of its kind. PLF litigates matters affecting the public interest at all levels of state and federal courts and represents the views of thousands of supporters nationwide. In furtherance of PLF's continuing mission to defend individual and economic liberties, the Foundation created its Free Enterprise Project. Through that project, the Foundation seeks to protect the free enterprise system from abusive regulation, the unwarranted expansion of claims and remedies in state civil justice systems, and barriers to the freedom of contract. To that end, PLF has participated in several cases before this Court and others on matters affecting the public interest, including issues related to the First Amendment and commercial speech. See, e.g., *Wine & Spirits Retailers, Inc. v. Rhode Island and Providence Plantations*, 128 S.

¹ Pursuant to this Court's Rule 37.2(a), all parties have consented to the filing of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of the Amicus Curiae's intention to file this brief. Letters evidencing such consent have been filed with the Clerk of the Court.

Pursuant to Rule 37.6, Amicus Curiae affirms that no counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than Amicus Curiae, its members, or its counsel made a monetary contribution to its preparation or submission.

Ct. 274 (2007); *Nike, Inc. v. Kasky*, 539 U.S. 654 (2003); *Fed. Election Comm'n v. Beaumont*, 539 U.S. 146 (2003); *Nixon v. Shrink Mo. Gov't PAC*, 528 U.S. 377 (2000); *Ark. Educ. Television Comm'n v. Forbes*, 523 U.S. 666 (1998). PLF attorneys also have published on the commercial speech doctrine. See, e.g., Deborah J. La Fetra, *Kick It Up a Notch: First Amendment Protection for Commercial Speech*, 54 Case W. Res. L. Rev. 1205 (2004). PLF believes its public policy experience will assist this Court in its consideration of the petition.

REASONS FOR GRANTING THE WRIT

In this Information Age, corporate communications represent a distinct and valuable voice, offering information that may be unavailable to other speakers, or information which other speakers (most notably the government) may choose not to reveal. Corporate speech contributes to public debates on matters of general interest, such as the economy, the environment, and foreign trade; and on matters of specific interest, such as the availability, usage, and effects of medical prescriptions, as in this case. Moreover, with greater frequency and subtlety, new technologies and innovative marketing strategies introduce the corporate profit-motive into what otherwise would be fully protected speech. The current commercial speech doctrine cannot predictably resolve disputes resulting from these new modes of expression.

In the past several decades, this Court's approach to speech uttered by business interests ranged from zero protection (*Valentine v. Chrestensen*, 316 U.S. 52 (1942)), to very high protection (*Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*,

425 U.S. 748 (1976)), to a four-part test (*Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980)), which has itself undergone revision (*Bd. of Trs. of the State Univ. v. Fox*, 492 U.S. 469, 480 (1989) (upholding a regulation outlawing Tupperware parties on a university campus)). The analyses differ depending on the speaker (*Bates v. State Bar*, 433 U.S. 350, 384 (1977), and *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978) (lesser protection accorded to attorney solicitations)) and the social worth of the activity promoted. *Compare Posadas de Puerto Rico Assocs. v. Tourism Co.*, 478 U.S. 328, 342, 348 (1986) (upholding restrictions on advertisements for legal gambling facilities), with *Vill. of Schaumburg v. Citizens for a Better Env't*, 444 U.S. 620, 632 (1980) (restrictions on solicitations for charity struck down). The divergent lines of commercial speech jurisprudence have produced a well of confusion, exemplified by the First Circuit's split decision in this case.

Corporate speech takes many different forms and addresses issues far beyond offering to sell widgets at low, low prices. Even when the speech is fairly straightforward in its attempt to bolster a bottom line, it is so frequently intermingled with otherwise protected speech that courts simply cannot determine where the speech falls in the tangled web of cases comprising the "commercial speech doctrine." In this case, the expressive activity is simply the compilation of factual data into reports for the purpose of providing that information, sometimes at a price, to those who value it. New Hampshire seeks to stifle this exchange of factual information, as a means of controlling free economic exchange. In an area of the law that is already full of almost incomprehensibly narrow

distinctions, only this Court can cut through the clutter. This case presents a perfect opportunity to do so.

ARGUMENT

I

THE LEVEL OF SCRUTINY APPLIED TO EXPRESSIVE CONDUCT BY BUSINESS INTERESTS PRESENTS A MATTER OF CRITICAL PUBLIC CONCERN

A. *Central Hudson* Has Proven Unworkable

The variety and pervasiveness of commercial and mixed commercial/noncommercial speech present in the market today cannot be analyzed adequately under the modern commercial speech doctrine. The decision below relies on this Court's cases, but in so doing, unmoors the precedents from the underlying source—the First Amendment. In *Central Hudson*, 447 U.S. at 566, this Court formulated a four-part test against which restrictions on commercial speech would be weighed:

For commercial speech to come within [the First Amendment], [1] it at least must concern lawful activity and not be misleading. Next, we ask [2] whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine [3] whether the regulation directly advances the governmental interest asserted, and [4] whether it is not more extensive than is necessary to serve that interest.

This Court later expanded *Central Hudson*'s inherent flexibility. See, e.g., *Bd. of Trs. of the State Univ. v. Fox*, 492 U.S. at 480 (requiring a "reasonable fit" rather than

the least restrictive means to comply with the fourth prong). Unfortunately, this flexibility has "left both sides of the debate with their own well of precedent from which to draw." Floyd Abrams, *A Growing Marketplace of Ideas*, Legal Times, July 26, 1993, at S28. See also Steven Shiffrin, *The First Amendment and Economic Regulation: Away from a General Theory of the First Amendment*, 78 Nw. U. L. Rev. 1212, 1222 (1983) ("commercial speech" was "an empty vessel into which content is poured").

Even this Court has been unable to apply the *Central Hudson* analysis in any predictable way. See, e.g., *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 419-20 (1993) ("This very case illustrates the difficulty of drawing bright lines that will clearly cabin commercial speech in a distinct category. . . . The absence of a categorical definition . . . is also a characteristic of our opinions considering the constitutionality of regulations of commercial speech."). Many lower courts have expressly noted their struggle to apply *Central Hudson*. See, e.g., *Nordyke v. Santa Clara County*, 110 F.3d 707, 712 (9th Cir. 1997) (striking down a fairground lease term prohibiting gun shows, appellate court described this Court's commercial speech cases, concluding that "*Central Hudson* is not easy to apply"); *Commodity Trend Serv., Inc. v. Commodity Futures Trading Comm'n*, 149 F.3d 679, 684 (7th Cir. 1998) (recognizing "the difficulty of drawing bright lines" (quoting *Discovery Network*, 507 U.S. at 419)); *Oxycal Lab., Inc. v. Jeffers*, 909 F. Supp. 719, 724 (S.D. Cal. 1995) (recognizing "that, often, these definitions will not be helpful and that a broader and more nuanced inquiry may be required"); see also *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 527

(1996) (Thomas, J., concurring) (courts have had difficulty in applying the *Central Hudson* balancing test "with any uniformity"). *Cf. Kasky v. Nike, Inc.*, 45 P.3d 243, 269 (Cal. 2002) (Brown, J., dissenting) ("[T]he commercial speech doctrine, in its current form, fails to account for the realities of the modern world—a world in which personal, political, and commercial arenas no longer have sharply defined boundaries."). *See also Am. Future Sys., Inc. v. Pa. State Univ.*, 752 F.2d 854, 867 (3d Cir. 1984) (Adams, J., concurring) ("The commercial speech doctrine, which offers lesser protection for commercial than for non-commercial communications, has been criticized almost since its inception for its failure to develop a hard and fast definition for this type of speech."). Moreover, this Court has noted the entreaties of "certain judges, scholars, and amici curiae" to repudiate *Central Hudson* and "implement[] a more straightforward and stringent test for assessing the validity of governmental restrictions on commercial speech." *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 184 (1999); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554 (2001).

The commercial speech doctrine as currently applied by this Court and lower courts can lead to highly unpredictable results, such as the decision below. Pulling a little of this and a little of that from a variety of this Court's opinions, and recognizing the expression under consideration was in "uncharted waters" (Pet. App. at 25) the First Circuit Court of Appeals developed a new doctrine unlike any this Court—or any other court—ever articulated. Pet. App. at 22-23 (holding that compilation and conveyance of truthful, factual information is conduct that falls outside the protection of the First Amendment). When the state of the law reaches this point, affected parties have no means by

which to adapt their actions or their speech to prevent themselves from running afoul of the law. This uncertainty chills protected speech as those fearing liability shy away from expression that might be construed as "commercial."

The confusion engendered by the opinion below weighs heavily in favor of this Court's review. Stability, certainty, and predictability are valued because they promote confidence in the rule of law and make the resolution of disputes a less costly enterprise. Joseph R. Grodin, *Are Rules Really Better Than Standards*, 45 Hastings L.J. 569, 570 (1994). Certainty achieves fairness to those who rely upon the law, efficiency in following precedent, and continuity and equality in treating similar cases equally. *McGregor Co. v. Heritage*, 631 P.2d 1355, 1366 (Or. 1981) (Peterson, J., concurring). Certainty promotes business innovation and development by letting firms know what they can and cannot do. Further, by eliminating speculation as to what the law is and avoiding a need for interpretation, clarification, or explanation, certainty promotes efficiency for businesses and individuals. Paul E. Loving, *The Justice of Certainty*, 73 Or. L. Rev. 743, 764 (1994).

B. Several Justices Recognized the Importance of Revisiting the Commercial Speech Doctrine in *Nike, Inc. v. Kasky*

This Court recognized the need to address the confusion generated by the commercial speech doctrine when it granted the petition for a writ of certiorari in *Nike, Inc. v. Kasky*, 537 U.S. 1099 (2003). The Court later dismissed the petition as improvidently granted, but several Justices nonetheless wrote to highlight the

magnitude of the issue, and the fact that it was not going away. *Nike, Inc. v. Kasky*, 539 U.S. 654. Justice Kennedy appended only a one-line opinion that the Court should not have dismissed the case. *Id.* at 665. But Justice Breyer's dissent, with Justice O'Connor concurring, argued that the case should have been decided on the merits and contains some intriguing suggestions regarding the evolving jurisprudence in the area of commercial speech. First, Justice Breyer acknowledged that the Court's refusal to issue an opinion on the merits may have the effect of causing corporations to refrain from speaking when they otherwise would participate in public dialogue. *Id.* at 667 ("In my view, however, the questions presented directly concern the freedom of Americans to speak about public matters in public debate, no jurisdictional rule prevents us from deciding those questions now, and delay itself may inhibit the exercise of constitutionally protected rights of free speech without making the issue significantly easier to decide later on."). Justice Breyer suggested that the principle guiding resolution of the case is the Court's previous recognition that speech on matters of public concern needs "breathing space" to survive. *Id.* at 676 (citing *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 272 (1964)). Based on the primacy of this principle, Justice Breyer would have applied heightened scrutiny to the statute challenged in *Nike*, and would further have held those provisions unconstitutional. *Id.*

Justice Breyer wrote particularly about the one of the nine challenged Nike communications that he thought veered closest to the "commercial speech" line (and thus least likely to warrant protection): a letter to university presidents and athletic directors. *Id.* at 676. Justice Breyer accepted this Court's characterization of the letter as one containing several commercial

elements: it was written by a commercial speaker to a commercial audience on the subject of the company's own business practices. *Id.* at 677. However, Justice Breyer found other, less commercial, elements more compelling: the letters were not in any kind of traditional advertising format, did not present or propose any commercial transaction, and "provide[d] 'information useful in discussions with concerned faculty and students.'" *Id.* Perhaps most importantly, "the letter's content makes clear that, in context, it concerns a matter that is of significant public interest and active controversy, and it describes factual matters related to that subject in detail." *Id.* Justice Breyer further noted that the facts asserted in the communication were central to the public debate, not peripheral. *Id.* at 678.

Having determined that these communications were worthy of heightened scrutiny, *id.*, Justice Breyer opined that "there is no reasonable 'fit' between the burden it imposes upon speech and the important governmental 'interest served.'" *Id.* at 679 (citation omitted). While finding public worth in false advertising statutes as a general matter, Justice Breyer was particularly troubled by the provision in the Unfair Competition Law that permits a private right of action without any showing of injury and regardless of whether the business acted intentionally. *Id.* Moreover, "[u]ncertainty about how a court will view these, or other, statements, can easily chill a speaker's efforts to engage in public debate At the least, they create concern that the commercial speaker engaging in public debate suffers a handicap that noncommercial opponents do not." *Id.* at 680 (citations omitted). Summing up the impact of the California Supreme Court's decision, Justice Breyer wrote that "[t]he upshot is that commercial speakers doing business in

California may hesitate to issue significant communications relevant to public debate because they fear potential lawsuits and legal liability." *Id.* at 682.

The California Supreme Court's split decision in *Kasky v. Nike* starkly revealed the disarray in this aspect of First Amendment jurisprudence. By accepting the petition, the Court embraced an opportunity to revisit the question: To what degree do we value corporate speech, and, consequently, to what degree will corporate speech be protected under the First Amendment? Unfortunately, when the Court dismissed the petition, the opportunity was set aside for another day.

The case presently before the Court offers an excellent opportunity to revisit the questions that have been postponed for six years and counting.

II

INNOVATIVE AND VALUABLE COMMERCIAL EXPRESSION DESERVES FULL FIRST AMENDMENT PROTECTION

A. "Common Sense" Does Not Suffice To Distinguish Commercial from Noncommercial Speech

Because the government may regulate commercial transactions, the government also assumes the ability to regulate commercial speech. See Rodney A. Smolla, *Information, Imagery, and the First Amendment: A Case for Expansive Protection of Commercial Speech*, 71 Tex. L. Rev. 777, 780 (1993). Yet "commercial speech" is not easily defined. See, e.g., *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 493 (1995) (Stevens, J., concurring) ("[T]he borders of the commercial speech category are

not nearly as clear as the Court has assumed."); *Edenfield v. Fane*, 507 U.S. 761, 765 (1993) ("[A]mbiguities may exist at the margins of the category of commercial speech."); and *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 81 (1983) (Stevens, J., concurring) ("[T]he impression that 'commercial speech' is a fairly definite category of communication . . . may not be wholly warranted."). These "ambiguities" threaten to overcome the rest of the category.

A profit motive, in and of itself, does not render speech unprotected. *Va. State Bd. of Pharmacy*, 425 U.S. at 761-62. Instead, relying on "common sense," the Court held that speech receives less-favored status only when it does "no more than propose a commercial transaction." *Id.* at 771 n.24. The two "common sense" distinctions are (1) that commercial speech is more verifiable than other types of speech and (2) that commercial speech is more durable than other types of speech. *Id.*, see also *Cent. Hudson*, 447 U.S. at 564 n.6. Both distinctions have been criticized by judges and scholars. See, e.g., Alex Kozinski & Stuart Banner, *Who's Afraid of Commercial Speech*, 76 Va. L. Rev. 627, 635-38 (1990); Donald E. Lively, *The Supreme Court and Commercial Speech: New Words with an Old Message*, 72 Minn. L. Rev. 289, 296-97 (1987); Robert Post, *The Constitutional Status of Commercial Speech*, 48 UCLA L. Rev. 1, 31-32 (2000).

One example of speech that is offered with a profit motive but which also has a genuine positive impact on public health matters is found on Web sites geared toward parents of infants and toddlers. Baby food manufacturers have Web sites chock full of helpful information as to when a baby should achieve developmental milestones, advice on how to encourage

a baby to eat new foods, health advice for the expectant and breastfeeding mother, and so on. Some even have a doctor on staff to answer e-mail inquiries. *See, e.g.*, Web site for Earth's Best Organic, Doctor's Corner, http://www.earthsbest.com/md_corner/index.php (last visited Apr. 9, 2009) (baby food company provides the services of an obstetrician/gynecologist and a pediatrician to answer consumers' questions online regarding everything from fertility and pregnancy to teething, allergies, and immunization). Of course, the Web sites also provide information for purchasing products, but one may peruse the sites at length without ever making a purchase. *See, e.g.*, Web site for Gerber products, at http://www.gerber.com/Expert_Advice/ (last visited Apr. 9, 2009) (pointing readers to information about nutritional development, new products, and expert advice, "24/7").

It is not always obvious to courts how to treat this type of mixed speech. *See, e.g., Name.Space, Inc. v. Network Solutions, Inc.*, 202 F.3d 573, 586 (2d Cir. 2000) (noting that domain names may or may not be commercial speech depending on a variety of factors). Thus the "common sense" distinctions no longer appear a solid foundation for diminished constitutional protection, and attempts to cram innovative methods of commercial expression into this rigid category leads only to confusion. The court below, purportedly applying common sense, nonetheless came to the non-sensical conclusion that the compilation of information from billions of drug prescriptions into reports that present the truthful information in a useful format, is of "scant social value." Pet. App. at 22.

**B. Corporate Speech Serves
Valuable Functions To Convey
Truthful Information and
Check Other Sources of Information**

Corporations play an important role in diffusing and checking societal and governmental accumulations of power. See David Millon, *The Sherman Act and the Balance of Power*, 61 S. Cal. L. Rev. 1219, 1243 (1988) ("Commercial opportunity meant more than just personal independence. Equally important, it guaranteed a balance of economic power in society.").

Viewed in this light, governmental suppression of corporate speech takes on potentially ominous implications for avoiding the centralization of political power. One can never be sure whether restrictions on corporate expression are in reality nothing more than governmental attempts to curb or intimidate a potential rival for societal authority.

Consider whether—under the First Circuit's theory in this case—the government could prohibit a private university's announcement, for the purpose of increasing enrollment (and thus, revenue), that it was forgoing government funding to avoid conditions attached to the money. If the government could prohibit this statement, on the purported public policy grounds of encouraging all universities to accept public funding and government priorities, not only would a certain element of democratically relevant information be unavailable to people, but "there would also be a legitimate fear that the government was seeking to suppress information concerning a particular commercial activity out of distaste for the values that it represents, and to ensure that more people did not partake in the activity and thereby increase its appeal."

Charles Fischette, *A New Architecture of Commercial Speech Law*, 31 Harv. J.L. & Pub. Pol'y 663, 680 (2008).

When the government silences speech, the vast majority of people will not know what they are missing. Ronald D. Rotunda, *The Commercial Speech Doctrine in the Supreme Court*, 1976 U. Ill. L.F. 1080, 1082-83. Legislators have an incentive to achieve their regulatory goals covertly, avoiding the normal political response. Fischette, *A New Architecture*, 31 Harv. J.L. & Pub. Pol'y at 685. The New Hampshire Legislature was very straightforward in its objective to stifle speech that promotes an activity the government disfavors, in an attempt to reduce that activity. By targeting the upstream communications, the government is able to hide its true purpose from all but the most intensely interested observers. See David A. Strauss, *Persuasion, Autonomy, and Freedom of Expression*, 91 Colum. L. Rev. 334, 335 (1991) ("[T]he government may not suppress speech on the ground that the speech is likely to persuade people to do something that the government considers harmful."). Excluding corporate speech from the First Amendment's reach thus has a detrimental impact on the most fundamental values underlying the protection of free speech. See Martin H. Redish & Howard M. Wasserman, *What's Good for General Motors: Corporate Speech and the Theory of Free Expression*, 66 Geo. Wash. L. Rev. 235, 264 (1998).

Corporate speech counteracts the dominance of the few media megacorporations, of government officials who can command free access to the press and other means of disseminating information simply by virtue of their position. See Kathleen M. Sullivan, *Political Money and Freedom of Speech*, 30 U.C. Davis L. Rev. 663, 686 (1997). Given that most individual citizens

either cannot, or choose not to, compete in public debates dominated by the press and the government, adding a component of corporate speech provides "a more diverse discourse than a debate dominated by two, so long as the third does not merely echo the others." David Shelledy, *Autonomy, Debate, and Corporate Speech*, 18 Hastings Const. L.Q. 541, 571-72 (1991).

Government may not silence one side of a public debate because it disagrees with it. *Erznoznik v. City of Jacksonville*, 422 U.S. 205 (1975); *Police Dep't of City of Chicago v. Mosley*, 408 U.S. 92 (1972). Relegating speech by those who have commercial interests to second-class status silences one side of a debate in just this way. In so doing, the government creates a bias in the democratic process designed to achieve the state's desired result, which is exactly the opposite of what the First Amendment is intended to do. Martin H. Redish, *First Amendment Theory and the Demise of the Commercial Speech Distinction: The Case of the Smoking Controversy*, 24 N. Ky. L. Rev. 553, 580 (1997). Moreover, silencing commercial speech "for the good of the citizenry" reflects a patronizing and offensive mistrust of citizens' ability to make personal choices based on the greatest range of information. James Weinstein, *Speech Categorization and the Limits of First Amendment Formalism: Lessons from Nike v. Kasky*, 54 Case W. Res. L. Rev. 1091, 1104-06 (2004).

Rational people need to listen to speech from both commercial and noncommercial sources with an equal amount of skepticism; even core political speech can be rife with falsehoods and misleading statements. See, e.g., *City of Farmers Branch v. Hawnco, Inc.*, 435 S.W.2d 288, 292 (Tex. Civ. App. 1968) ("[P]ublic officials are not legally required to keep their campaign

promises and whether they do or not they are answerable to the voters at the next election."'). Most, if not all, speakers have some self-interest, whether financial or personal, in having their views accepted by their audience. This self-interest does not diminish the First Amendment protection sheltering "political candidates seeking elective office, consumer organizations seeking increased consumer protection, welfare recipients seeking increases in benefits, farmers seeking subsidies, and American auto workers seeking higher tariffs on foreign automobiles." Redish & Wasserman, 66 Geo. Wash. L. Rev. at 269-70. Instead, First Amendment values of truth-seeking and democratic participation are advanced when the substance of the debate contains elements from all interested parties. The simple fact that all sides of a debate can participate is "likely to spur expression's thoroughness, thoughtfulness, and breadth of distribution. To exclude all self-interested expression from the scope of the constitutional guarantee, then, would effectively gut free speech protection." *Id.*

CONCLUSION

While hard cases may make bad law, sometimes "it is bad law that is creating the hard cases." Ashutosh Bhagwat, *Hard Cases and the (D)Evolution of Constitutional Doctrine*, 30 Conn. L. Rev. 961, 984 (1998). *Central Hudson* falls into this category. Until this Court simplifies First Amendment jurisprudence by protecting commercial speech, lower courts will continue to struggle and the citizenry will be deprived of all sides of important controversies. The decision of the First Circuit Court of Appeals cannot be reconciled

with the First Amendment. It can only serve as authority for other courts to ratchet downward the protection due not only to commercial speech, but to any speech that has even the slightest element of commercial gain for the speaker. The petition for a writ of certiorari should be granted.

DATED: April, 2009.

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IN THE
Supreme Court of the United States

IMS HEALTH, INC. *et al.*,

Petitioners,

v.

AYOTTE,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

**BRIEF OF AMICI CURIAE PHARMACEUTICAL
RESEARCH AND MANUFACTURERS OF AMERICA
(PhRMA) AND BIOTECHNOLOGY INDUSTRY
ORGANIZATION (BIO) IN SUPPORT OF PETITIONERS**

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Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Industry Organization (BIO), as *amici curiae*, urge that the Court grant the writ of certiorari requested by Petitioners because the ruling below impairs not only Petitioners' First Amendment rights, but also those of PhRMA's and BIO's members.¹

INTEREST OF *AMICI CURIAE*

PhRMA is a voluntary, non-profit association that represents the country's leading pharmaceutical and biotechnology research companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.² PhRMA member companies are leading the search for new cures. In 2008, PhRMA members invested approximately \$50.3 billion to develop new medicines. PhRMA's mission is to advocate policies that encourage these efforts by

¹ The parties have consented in writing to PhRMA's and BIO's participation. Copies of those consents have been filed with the Clerk of the Court. Counsel of record for all parties received notice of PhRMA's and BIO's intention to file an *amicus curiae* brief at least 10 days prior to the due date for this *amicus curiae* brief. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission.

² A list of PhRMA's current membership can be found at http://www.phrma.org/about_phrma/member_company_list/members/.

pharmaceutical and biotechnology research companies to create life-saving and life-enhancing new medications for patients.

BIO is the world's largest biotechnology organization, providing advocacy, business development, and communications services for more than 1,250 members.³ BIO members include biotechnology companies, academic institutions, state technology centers, and related organizations in the United States and more than 30 other nations. BIO members are involved in research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products. A majority of BIO members engage in biomedical research, and to date, such companies have introduced 254 new medicines.

PhRMA and BIO are well situated to address the issues presented in this petition. The restrictions in New Hampshire's "Prescription Information Law," N.H. Rev. Stat. Ann. § 318:47-f, are intended to obstruct important communications by biopharmaceutical manufacturers (including PhRMA and BIO members) using prescriber data, including communications designed to market their drugs efficiently. The Prescription Information Law also hampers biopharmaceutical manufacturers in targeting scientific and safety messages at health care providers who most need information about particular drugs. Moreover, the Prescription Information Law may make it economically infeasible for Petitioners to publish this data, effectively

³ A list of BIO's current membership is at <http://bio.org/members/biomembers.asp>.

denying this information to research organizations (including BIO members) who previously received it free of charge.

Although the Prescription Information Law does not by its terms regulate or penalize biopharmaceutical manufacturers, its intended effect is to restrict the discussions that biopharmaceutical company representatives have with physicians — in the words of the parallel statute enacted in Vermont, to rectify a perceived imbalance in “the marketplace of ideas.” Vermont Act 80, § 1(4). In determining that the Prescription Information Law regulates only conduct, the First Circuit ignored the intent of the New Hampshire Legislature not only to restrict speech of biopharmaceutical manufacturers, but to do so based on the viewpoint they express — the most invidious form of First Amendment violation. Particularly given that three states have enacted, and another 14 are considering, similarly discriminatory legislation, PhRMA and BIO have a significant interest in this Court’s resolution of the issues, before the First Circuit’s erroneous decision encourages further infringements on the free speech of their members.

SUMMARY OF ARGUMENT

The purpose and effect of the Prescription Information Law is to facilitate speech the government favors and to obstruct speech it dislikes. The First Amendment does not permit such government incursions on free speech. Although the Prescription Information Law does not directly bar biopharmaceutical manufacturers from using prescriber

data, it prohibits Petitioners from selling the information to them — but only if the manufacturers use it to promote their drugs. At the same time, the Prescription Information Law permits transfer of the data to speakers besides manufacturers for commercial uses in influencing doctors *not* to prescribe brand-name drugs. The legality of the transfer therefore depends on the identity of the customer and what the customer communicates.

This restriction of the truthful speech of biopharmaceutical manufacturers cannot withstand intermediate scrutiny, because the State cannot establish that it directly advances substantial state interests in a manner no more extensive than necessary. Rather than undertaking the searching inquiry this Court has mandated, the First Circuit shifted the burden of proof to Petitioners and even then assessed only whether the law was “reasonably calculated” to advance the State’s asserted interests. Proper application of intermediate scrutiny demonstrates that the Prescription Information Law does not directly advance the State’s asserted interests and is far more extensive than necessary.

ARGUMENT

I. The Intent And Effect Of The Prescription Information Law Is To Restrict Speech Of Biopharmaceutical Manufacturers

A. The Prescription Information Law Seeks To Suppress Speech On The Basis Of Viewpoint

In upholding the Prescription Information Law, the First Circuit concluded that the Petitioners' "acquisition, aggregation and sale" of prescribing history information, Pet. App. 16, described as "upstream" activity, was not speech, Pet. App. 12, 26.⁴ Petitioners have demonstrated that their communication of prescribing histories to biopharmaceutical manufacturers and others is in fact speech protected by the First Amendment. But of more pressing import to PhRMA and BIO, the First Circuit also erred in its alternative evaluation of the "downstream" effect of the Prescription Information Law on speech between biopharmaceutical manufacturers and physicians. The First Circuit conducted this analysis even after acknowledging that, because "no detailer or doctor is a plaintiff here," judicial restraint counseled that "adjudication of that aspect of the law . . . await a proper plaintiff." Pet. App. 24.

⁴ The District Court in Vermont reached a contrary result, concluding that "prescriber identifiable data is protected 'speech' under the First Amendment." *IMS Health Inc. v. Sorrell*, Case 1:07-cv-00188-jgm, 2009 WL 1098474, at *5 (D. Vt. Apr. 23, 2009).

Indeed, the central purpose of the Prescription Information Law is to restrict the speech of biopharmaceutical manufacturers. As Judge Lipez noted in his concurrence/dissent, “the New Hampshire Legislature chose to regulate the upstream transactions because it *wanted to alter the message* used by pharmaceutical detailers in pursuing a downstream transaction with health care professionals. In other words, the Act was *designed to limit the speech* of those detailers.” Pet. App. 51 (emphasis added); *see also IMS Health, Inc. v. Sorrell*, 2009 WL 1098474, at *6 (“Plainly, the whole point of section 17 is to control detailers’ commercial message to prescribers.”).

That this issue arises in the context of healthcare cannot obscure the First Amendment violation. If the State had barred the sale of Nielsen ratings to fast food advertisers to prevent them from targeting shows that appeal to young adults, there would be no doubt the restriction violated the First Amendment, even though it did not directly regulate advertisers. The Prescription Information Law is at least as serious an infringement of speech. Although it does not directly bar biopharmaceutical manufacturers from using prescriber information or impose penalties on them, it prevents entities like Petitioners from selling it to them for use in promoting their drugs. Depriving a speaker of the tools to speak effectively, for the express purpose of preventing it from delivering a particular message, violates the First Amendment. *Cf. Grosjean v. Am. Press Co.*, 297 U.S. 233, 250 (1936) (license tax violated First Amendment “because, in the light of its history and of its present setting, it is seen to be a deliberate and calculated device in the guise of a tax to limit the

circulation of information to which the public is entitled"); see generally *Minneapolis Star & Tribune Co. v. Minn. Comm'r of Revenue*, 460 U.S. 575, 585 (1983) ("[D]ifferential treatment, unless justified by some special characteristic of the press, suggests that the goal of the regulation is not unrelated to suppression of expression, and such a goal is presumptively unconstitutional."); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 564 (2001) (restrictions on modes of advertising violated First Amendment).

New Hampshire's discrimination based on the viewpoint of speech is flagrant. The Prescription Information Law prohibits transfer of prescriber data for purposes of promoting sales of prescription drugs, but permits it for other purposes that influence a doctor's prescribing decision and further the commercial interests of speakers, such as the State and health insurers. See Pet. App. 77 ("In effect, the statute prohibits the use of prescriber-identifiable data for all purposes related to detailing, but seeks to preserve access to the data for other uses — including commercial purposes." (Lipez, J., concurring in part, dissenting in part)). To put it starkly, the Prescription Information Law bars Petitioners from selling their prescriber identifiable data to a biopharmaceutical manufacturer that seeks to use it to tell a New Hampshire doctor, "Prescribe this drug." But Petitioners could sell the same information to an insurance company that, with no less commercial motive, could use it to tell the same doctor, "Do not prescribe this drug." The First Amendment does not allow the government to facilitate speech it favors and obstruct speech it disfavors. See *Greater New Orleans Broad. Ass'n v.*

United States, 527 U.S. 173, 193-94 (1999) (noting impermissibility of choosing between speakers in commercial marketplace).

The First Circuit condoned this favoritism in concluding that New Hampshire could properly seek to “level the playing field” of speech concerning pharmaceutical products by restricting the communications of one of the players, biopharmaceutical manufacturers. Pet. App. 25. Such legislative control of the *free* marketplace of ideas is no more permissible than if the state barred advertising by brand-name soda companies to “level the playing field” for store brand soda. A state cannot ban speech — including commercial speech — simply because it is effective. As Justice Brandeis recognized, the essential feature of the marketplace for ideas is that if one viewpoint is prevailing, “the remedy to be applied is more speech, not enforced silence.” *Whitney v. California*, 274 U.S. 357, 377 (1927) (Brandeis, J., concurring). In particular, the government may not impede the dissemination of truthful information based on a paternalistic view that the speech may lead others — in this case, trained medical professionals — to make certain decisions. See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002) (“We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.”); 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (“The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.”);

Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976) ("It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if freely available, that the First Amendment makes for us."); see also *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) ("[T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented."); *Greater New Orleans*, 527 U.S. at 195 (noting "presumption that the speaker and the audience, not the Government, should be left to assess the value of accurate and nonmisleading information about lawful conduct").

B. The Prescription Information Law, As The Legislature Intended, Would In Fact Obstruct The Free Speech Of Biopharmaceutical Manufacturers

The premise underlying the Prescription Information Law is that biopharmaceutical manufacturers use prescription histories to target physicians for sales calls and to tailor sales presentations to the practice of those physicians. By denying data to biopharmaceutical companies, the State theorizes, the Prescription Information Law will deprive the companies of this "advantage," making the messages conveyed less individualized and hence less effective. In other words, the ban will force biopharmaceutical manufacturers to change their speech to prescribing physicians.⁵

⁵ To be sure, Petitioners feel the immediate brunt of New Hampshire's effort to suppress the lawful and non-misleading
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Because of the restrictions imposed on entities such as Petitioners, biopharmaceutical companies will no longer have information on the prescribing history of individual New Hampshire doctors to facilitate discussions between detailers and doctors in New Hampshire, to provide doctors the most useful scientific information, and to focus on those doctors — such as the ones who prescribe the drug most frequently — who will derive the greatest benefit from learning more about the drug. In restricting truthful messages that biopharmaceutical manufacturers, guided by prescriber

(Cont'd)

speech of biopharmaceutical manufacturers. The statute directly limits Petitioners' ability to speak; it bars them from communicating the information they collected, based on the downstream speech of their clients. Petitioners' communications, New Hampshire has determined, enable biopharmaceutical companies to sharpen their messages to physicians. By choking off Petitioners' communications to manufacturers, New Hampshire seeks to choke off the communications of manufacturers to doctors. Both levels of restriction violate the First Amendment. Both are interconnected, and — contrary to the First Circuit's holding on standing — both were appropriately part of Petitioners' claims. *Craig v. Boren*, 429 U.S. 190, 194 (1976) (Article III standing because statute inflicts "a direct economic injury through the constriction of [the] buyers' market"); *Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004) (Court is "quite forgiving with these criteria [for third-party standing] in certain circumstances," including First Amendment cases); *Sec'y of State of Md. v. Joseph H. Munson Co.*, 467 U.S. 947, 958 (1984) (third-party standing because "[t]he activity sought to be protected is at the heart of the business relationship between [plaintiff] and its clients, and [plaintiff's] interest in challenging the statute are completely consistent with the First Amendment interests of the [third parties] it represents").

identifiable data, convey to physicians, the Prescription Information Law may render detailing visits less efficient and less informative, which means that New Hampshire physicians could be deprived of information on new medications.

Indeed, that is the intended purpose of the statute. But the unintended consequence may be that Petitioners and other entities covered by the Prescription Information Law stop transferring prescribing data to biopharmaceutical manufacturers for *any* purpose, commercial or otherwise, for fear of being held responsible if companies in fact use the data commercially. In addition to using the prescriber data for marketing, biopharmaceutical manufacturers use these data to prioritize the release of public safety news alerts, including alerts regarding newly discovered side-effects; to disseminate information to prescribers; to implement prescription recall programs; to determine which products to develop and license; and to accelerate the development of new drugs based on the needs of the marketplace. Pet. App. 74 n.29 (citing Stipulation of Facts at 4-5), 107.⁶ The Prescription Information Law may make prescriber data unavailable for these non-marketing uses. Moreover, if Petitioners cannot, as a

⁶ Because biopharmaceutical companies use prescriber data for these non-marketing purposes, any commercial aspect of their communications using this data is "inextricably intertwined with otherwise fully protected speech." The communications are therefore subject to strict scrutiny. *Riley v. Nat'l Fed'n for the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988). As the Prescription Information Law cannot survive intermediate scrutiny, see pp. 13-23, *infra*, it follows *a fortiori* that it cannot withstand strict scrutiny.

practical matter, sell biopharmaceutical companies their data on New Hampshire physicians, it is not clear that it will be economically feasible for them to publish the data at all. The result could be that many non-profit and research organizations — who have received this information free of charge — will also no longer have access to it. That result would further undermine the public health.

The adverse impact of the First Circuit's validation of the Prescription Information Law may spread beyond New Hampshire. Similar statutes in two other states have already been challenged: (1) in Maine, the district court enjoined the statute, and the appeal was stayed pending the First Circuit's decision on the Prescription Information Law; and (2) in Vermont, the district court held that the statute restricted the speech of both data publishers and biopharmaceutical manufacturers, but satisfied intermediate scrutiny. The District Court in Vermont relied extensively on the First Circuit decision in this case, thus repeating the same errors. *See, e.g., IMS Health, Inc. v. Sorrell*, 2009 WL 1098474, at *8, *10, *12. Legislation is pending in approximately 14 other states. Notwithstanding the idiosyncrasies of the New Hampshire statute and First Circuit precedent, legislatures in other states may view the decision below as a green light to abridge the free speech of biopharmaceutical manufacturers. However misguided these judgments may be, the failure of this Court to provide clarity now could result in additional burdens on the First Amendment rights of biopharmaceutical manufacturers. It could also place this Court in the position of having ultimately to invalidate the laws of many states rather than just one.

II. The Prescription Information Law Cannot Withstand Intermediate Scrutiny Under *Central Hudson*

A. The First Circuit Did Not Undertake The Searching Inquiry Required By *Central Hudson*

Central Hudson and its progeny put the burden on the State to establish that a restriction of truthful, non-misleading commercial speech "directly" advances "substantial" state interests in a manner "not more extensive than is necessary to serve that interest." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980); see also *44 Liquormart*, 517 U.S. at 508-12; *Thompson*, 535 U.S. at 371-73. The First Circuit was not true to *Central Hudson* here. Instead, the Court invented a standard more akin to rational basis review. For example, rather than evaluating whether the State had proven that the Prescription Information Law "directly advanced" the professed goal of reducing health care costs, *Central Hudson*, 447 U.S. at 566, the First Circuit considered only whether "the state adequately demonstrated that the Prescription Information Law is *reasonably calculated* to advance its substantial interest in reducing overall health care costs within New Hampshire." Pet. App. 38. Under this standard, the State could abridge free speech if it rationally but wrongly thought that doing so would somehow further the State's interest.

Moreover, instead of considering whether the State had established that the Prescription Information Law

was “not more extensive than necessary to serve that interest,” *Central Hudson*, 447 U.S. at 566, the First Circuit evaluated only whether Petitioners had “identified an alternative to the Prescription Information Law that promises to achieve the goals of the law without restricting speech.” Pet. App. 41. It was not Petitioner’s burden, however, to identify such alternatives. This Court has repeatedly held that this burden resides with the State. *See, e.g., Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) (“Government carries the burden” of justifying law regulating commercial speech.); *Edenfield*, 507 U.S. at 762 (Government has burden of showing “the harms it recites are real and that its restriction will in fact alleviate them.”).

Intermediate scrutiny under the First Amendment demands a far more rigorous inquiry into the reliability and substantiality of the evidence supporting the restriction on speech. *See, e.g., Gonzales v. Carhart*, 550 U.S. 124, 165 (2007) (“The Court retains an independent constitutional duty to review factual findings where constitutional rights are at stake.”); *Sable Commc’ns of Cal., Inc. v. FCC*, 492 U.S. 115, 129 (1989) (“Deference to a legislative finding cannot limit judicial inquiry when First Amendment rights are at stake.” (internal quotations omitted)). It requires a searching and independent review. The First Circuit’s review was not searching. It was not independent. And it was not the inquiry demanded by *Central Hudson*. Had the Court undertaken the requisite assessment—which Petitioners in fact had standing to pursue—it could not have upheld the Prescription Information Law.

B. The Prescription Information Law Does Not Directly Advance The State's Asserted Interests And Is Far More Extensive Than Necessary

The State's asserted interest in the Prescription Information Law is lowering health care costs. Relying on speculation, the Legislature postulated that prohibiting the transfer of prescriber data would make detailers less persuasive in speaking with physicians. That poorer advocacy would result in physicians prescribing fewer of the more-expensive brand-name drugs. That, in turn would lower health care costs. This chain of causation contains only weak links.

First, it is inappropriate to consider only the costs of prescription drugs, as New Hampshire did, and not to assess whether appropriate use of those drugs lowers other health care costs. Thus, the Legislature should have assessed whether non-drug treatments are available, whether particular brand-name drugs are more effective, whether they reduce expensive hospitalizations, whether they improve quality of life, and whether they extend life.⁷ No authority suggests

⁷ Available empirical evidence demonstrates that use of newer drugs decreases total treatment costs, increases longevity, and improves quality of life. See, e.g., Frank R. Lichtenberg, *The Effect of Using Newer Drugs on Admissions of Elderly Americans to Hospitals and Nursing Homes: State-level Evidence from 1997 to 2003*, 24 SUPPL. 3 PHARMACOECONOMICS 5, 21-23 (2006) (as age of drugs in therapy increased, hospital admissions and expenditures increased and discharges decreased); Frank R. Lichtenberg, *Are the Benefits of Newer* (Cont'd)

that a state has a legitimate interest, much less a substantial one, in lowering what it or the public pays for prescription drugs, without considering the consequent costs and burdens.

Even if the State's narrow focus on reducing the amount of brand-name drugs prescribed in New Hampshire did delimit an appropriate state interest, New Hampshire had to show that the Prescription Information Law "directly advance[d]" that interest. *Central Hudson*, 447 U.S. at 564 (emphasis added). The key word is "directly."

This Court made clear in *Central Hudson* that "the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose." *Id.* The Court reiterated in *Edenfield* that "mere speculation or conjecture" is insufficient to fulfill these requirements. 507 U.S. at 770. And, in *Rubin*, the Court emphasized that this requirement is "critical;

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Drugs Worth Their Cost? Evidence from the 1996 MEPS, 20 HEALTH AFFAIRS 241, 248 (2001) (as usage of newer drugs increases, reductions in non-drug expenditures greatly exceeds increase in drug expenditures, yielding net decrease of health care expenditures); Frank R. Lichtenberg, *The Value of New Drugs: The Good News in Capsule Form*, THE MILKIN INSTITUTE REVIEW, Fourth Quarter 2003, 22-25 (2003) (prescribing newer drugs increased longevity, decreased total treatment costs, and improved quality of life); Frank R. Lichtenberg, *The Effect of New Drug Approvals on HIV Mortality in the US, 1987-1998*, 1 ECONOMICS AND HUMAN BIOLOGY 259, 265 (2003) (increase in new drugs for HIV played key role in decline of HIV mortality).

otherwise, 'a State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.'" 514 U.S. at 487 (quoting *Edenfield*, 507 U.S. at 771); see also *Va. State Bd. of Pharm.*, 425 U.S. at 766-68 (ban on advertising drug prices would not directly advance state's goals of maintaining professionalism among licensed pharmacists and protecting patient health); *Bates v. State Bar of Ariz.*, 433 U.S. 350, 368, 377 (1977) (advertising ban would not protect quality of attorneys' work but would increase legal fees). The First Circuit's holding, however, permits experimental infringements on protected speech — infringements based on hope and conjecture. See Pet. App. 36-37 ("[W]e must allow the state legislature some leeway to experiment with different methods of combating a social and economic problem of growing magnitude."). In failing to require actual proof that such restrictions would directly advance the government's interest, the First Circuit strayed from the precedents of this Court, see *Edenfield*, 507 U.S. at 770, and of other Circuits. See, e.g., *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 100 (2d Cir. 1988) (state must "marshal[] some empirical evidence to support its assumptions");⁸ *Midwest Media Prop., L.L.C. v. Symmes Tp., Ohio*,

⁸ Relying exclusively on the First Circuit's decision in this case, the District Court of Vermont mistakenly failed to address this controlling Second Circuit precedent. See *IMS Health Inc. v. Sorrell*, 2009 WL 1098474, at *12 ("[E]mpirical evidence is not a requirement to withstand the intermediate scrutiny of *Central Hudson* in a case such as this." (citing *IMS Health v. Ayotte*, 550 F.3d 42, 55-59 (1st Cir. 2008))). Thus, this decision is already creating confusion in other courts.

503 F.3d 456, 475 (6th Cir. 2007) (standard "depends neither on obviousness nor common sense" but "requires *some* evidence to establish that a speech regulation addresses actual harms with some basis in fact"); *Mason v. Fla. Bar*, 208 F.3d 952, 957-58 (11th Cir. 2000) (noting need for actual evidence).

As the District Court correctly found, New Hampshire did not make the showing *Central Hudson* requires. First, there is no evidence that restricting the transfer of prescriber data to biopharmaceutical manufacturers to prevent sales representatives from tailoring their presentations to individual physicians will actually reduce prescriptions of brand-name drugs. Physicians, not surprisingly, base prescribing decisions on a variety of factors specific to each patient, such as age, allergies, prior responses to drugs, and the like. Physicians obtain information for these decisions from various sources, not merely from in-person meetings with pharmaceutical representatives. In the decades that detailers have called on physicians, no state has previously sought to restrict these communications as New Hampshire has. Thus, the Legislature's prediction that doctors will change their behavior in the face of such restrictions rests on no historical experience.

In the place of experience, the State relies on two paternalistic assumptions to support its assertion that restricting communication of truthful information to physicians will decrease inappropriate prescribing of brand-name drugs: *one*, that the State cannot trust highly trained, well-educated, medical professionals to make appropriate decisions regarding which drugs to prescribe to their patients, and *two*, that without the

paternalistic protection of the State, these trained medical professionals cannot resist the wiles of detailers. The overbreadth of these assumptions highlights their logical infirmity. They apply across the board, no matter how accomplished the physician, no matter how powerful the drug, no matter how truthful and honest the sales representative, and no matter how onerous the federal criminal penalties for false or misleading statements in the marketing of prescription drugs. *See* 21 U.S.C. §§ 321(m), 331(a), 333(a), 352(a) (2007); 21 C.F.R. § 202.1 (2008).

Second, as noted, the Prescription Information Law would make detailing less efficient, because biopharmaceutical companies could not determine with the same accuracy which prescribers most want to hear about a given product. Companies could well respond by having sales representatives call on more physicians, including physicians whom prescriber data previously indicated were unlikely to be interested, to ensure that they still reach those who are interested and who would benefit from the meeting. The inefficiency could increase marketing costs, but there is no explanation of how or why that would translate into reduced healthcare costs. Indeed, the Legislature had no empirical evidence that its restrictions would lower the overall cost of prescription drugs. *See* Pet. App. 192 ("Because the Attorney General has failed to prove that any reductions in health care costs that may result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care, I am unable to endorse her argument that the Prescription Information Law can be justified as a cost containment measure.").

Third, as discussed, the Prescription Information Law targets only one subset of healthcare expenditures. If the restriction caused doctors to prescribe fewer brand-name drugs than is optimal, overall health expenditures could increase, even if prescription drug costs decrease. Again, the Legislature had no empirical evidence whatsoever suggesting that the Prescription Information Law would decrease overall health care costs. *See id.*

Central Hudson also demands that the State demonstrate a reasonable fit between the limitation on speech and the interest asserted — *i.e.*, that the restriction is narrowly tailored to achieve the desired objective. *Lorillard*, 533 U.S. at 528. This Court has instructed that if a state “could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.” *Thompson*, 535 U.S. at 371; *see also id.* at 373 (“If the First Amendment means anything, it means that regulating speech must be the last — not the first — resort.”); 44 *Liquormart*, 517 U.S. at 509-10 (“*Posadas* clearly erred in concluding that it was ‘up to the legislature’ to choose suppression over a less speech-restrictive policy.”). In *Central Hudson*, this Court invalidated a ban on advertising of electricity because, though important, the government’s interest in reducing the use of energy did not “justify suppressing information about electric devices or services that would cause no net increase in total energy use.” 447 U.S. at 570. The Prescription Information Law similarly imposes a sweeping ban on the transfer of prescriber data for commercial use by biopharmaceutical companies and fails to differentiate between beneficial and “harmful” detailing.

Biopharmaceutical companies market their products in many ways. In restricting the transfer of prescriber-identifiable data, the Prescription Information Law addresses, albeit indirectly, only one of them — visits to physicians by sales representatives. Detailers' meetings with physicians can be helpful and scrupulously candid. Or they might be unhelpful and lacking in candor. If so, the physician likely would not invite the sales representative back and the representative could be subject to federal law penalties if the information presented is found to be untruthful, inaccurate, or misleading. But the Prescription Information Law draws no distinction between truth and falsity. It prevents both candid and un-candid sales representatives from using prescriber-identifiable data. The Prescription Information Law thus prevents helpful, honest detailing by sales representatives who use prescriber-identifiable data, while leaving untouched any unhelpful sessions by detailers who do not use such information. Insofar as New Hampshire seeks to ensure that physicians receive appropriate information about prescription drugs, the Prescription Information Law is both over- and under-inclusive. Moreover, though designed to encourage prescribing of cheaper generic drugs instead of expensive brand-name products, the Prescription Information Law applies even when a brand-name drug has no generic equivalent, when two brand-name drugs are being compared, and when an improved version of a brand-name drug is being compared to its earlier version. And, though designed to decrease the cost of healthcare, the Prescription Information Law restricts speech even when the brand-name drug is not the most expensive treatment. Indeed, it restricts speech even when the

use of a brand-name drug would reduce overall healthcare costs.

This was not a case where New Hampshire exhausted its other options. The State failed even to test obvious alternatives to the Prescription Information Law which do not restrict speech. The State could have addressed its concerns by, for example, implementing an academic detailing program to inform physicians about generic drugs and about the methods used to market prescription drugs.⁹ The State could have required prescribers to receive training about marketing as a part of their continuing medical education. It could have sent "Dear Healthcare Professional" letters to educate prescribers. It could have more aggressively implemented measures such as comprehensive drug formularies, prior authorization, and step therapies. And it could have supported industry ethical codes. Although the dissent touted the resources that biopharmaceutical companies devote to marketing, the Court did not consider, and the Legislature made no effort to evaluate, the vast resources of the health insurance industry, which has every incentive to discourage prescribing of brand-name drugs.

⁹ Since enactment of the Prescription Information Law, New Hampshire has required the development of an "evidence-based prescription drug education program." N.H. Rev. Stat. Ann. § 126-A:5(XVII) (eff. June 3, 2008). However, the Legislature did not implement and test the effectiveness of this option before enacting the Prescription Information Law.

As noted, rather than requiring New Hampshire to show why these less restrictive and more direct means of advancing the State's interests were inadequate or infeasible, the First Circuit imposed the onus on Petitioners to establish the superiority of less restrictive alternatives. *See* Pet. App. 41. But under the First Amendment, the speaker does not have to prove that its free speech should be protected. Rather, the state must justify its abridgement of First Amendment rights. *See Edenfield*, 507 U.S. at 770. As this Court has made clear, plaintiffs only needed to show that other less restrictive means "might be possible." *Thompson*, 535 U.S. at 372. It was the State's burden to show that they were not.

To let the First Circuit's revision of the *Central Hudson* test stand would countenance infringement of the First Amendment rights of both Petitioners and biopharmaceutical manufacturers. It could also signal to other states that federal courts need *not* undertake the "independent and searching inquiry" mandated by *Central Hudson* into First Amendment violations, that any "limitation on expression" need not be "designed carefully to achieve the State's goal," *Central Hudson*, 447 U.S. at 564, and that states need not constrain their intervention into the commercial marketplace of ideas. This Court should grant review now to prevent these affronts, rather than risk having to undo them later.

CONCLUSION

For the foregoing reasons, the Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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No. 08-1202

IN THE
Supreme Court of the United States

IMS HEALTH INC. & VERISPAN, LLC.,

Petitioners,

v.

KELLY A. AYOTTE, NEW HAMPSHIRE ATTORNEY
GENERAL,

Respondent.

On Petition for Writ of Certiorari to the
United States Court of Appeals
for the First Circuit

BRIEF OF SOURCE HEALTHCARE
ANALYTICS, INC. AS *AMICUS CURIAE*
IN SUPPORT OF PETITIONER

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STATEMENT OF INTEREST¹

Source Healthcare Analytics, Inc., sells a variety of information products, including products addressed by New Hampshire's Prescription Restraint Law ("the Law").² These products utilize prescriber-identified prescription information (omitting the identity of the patient), organized and presented in various ways, and/or combined with other information, to meet the needs of particular user groups.

One use of *Amicus's* products covered by the Law is to enable pharmaceutical companies to identify doctors who may be interested in their products, and to provide relevant information to sales representatives who regularly meet with individual doctors. These products also enable pharmaceutical companies to identify doctors who may have patients who would be suitable participants in clinical trials of new drugs. These products have been used by

¹ Pursuant to Supreme Court Rule 37.6, *Amicus* states that no counsel for any party authored this brief in whole or in part, and that no person or entity other than Source Healthcare Analytics, Inc., has made a monetary contribution to fund the preparation or submission of this brief. Counsel for all parties received notice more than 10 days prior to the filing of this brief, and both Petitioner and Respondent consented to its filing.

² Source Healthcare Analytics, Inc. is a wholly-owned subsidiary of Wolters Kluwer Health, Inc., which is a division of Wolters Kluwer U.S. Corporation. While not a plaintiff in the instant litigation, Source Healthcare Analytics, Inc., is a plaintiff in pending litigation in Maine and Vermont raising similar constitutional issues. See *IMS Health, Inc., et al. v. Steven Rowe*, No. 07-cv-127 (D. Me., filed Aug. 29, 2007); *IMS Health, Inc. v. William H. Sorrell*, No. 07-cv-188 (D. Vt., filed Aug. 29, 2007).

governmental agencies, including the FDA, to direct safety alert letters to doctors whose prescribing practices make them relevant, and to enforce civil and criminal laws against abusive prescribing practices. Governmental agencies have also used these informational products to perform regulatory impact studies which assess the effect of labeling changes on prescribing habits and usage patterns.

The First Circuit's decision would strip these products—and the valuable information they contain—of *any* protection under the First Amendment. It is unsurprising that the First Circuit's crabbed concept of what constitutes "speech" conflicts with settled precedent of this Court and with the decisions of other courts of appeals. The decision below would greatly hinder the free dissemination of essential information in the modern marketplace—of both commerce and ideas. For this reason, Source Healthcare Analytics files this brief as *amicus curiae*, urging the Court to grant the Petition and correct the decision below.

SUMMARY OF THE ARGUMENT

The First Circuit's holding that the New Hampshire statute is not a regulation of speech that must be analyzed under the First Amendment is obviously incorrect.

The transfer of truthful information from one person to another, with the expectation that the information will be used by the recipient to inform his legitimate business dealings, is near the heart of any reasonable concept of protected speech. The

information covered by the New Hampshire law bears no resemblance to obscenity, discriminatory threats and proposals of collusive, anticompetitive behavior—which the First Circuit used as an analogy to deny this information any First Amendment protection. The general rule is that the speaker and the audience assess the value of truthful, commercial information—not the government. Here, the dialogue between a pharmaceutical representative and a doctor permits the doctor to make informed decisions about what drugs to prescribe to his or her patients. This communication is protected by the First Amendment. In much the same way, the communication of information from *Amicus* and Petitioners to a pharmaceutical company to inform that very dialogue is also speech, whose restriction demands First Amendment scrutiny.

The State's efforts to affect the ultimate commercial speech by regulating the information that underlies that speech—and the First Circuit's express authorization of that approach—conflicts with a long and unbroken line of this Court's precedent. Governmental impairment of activities incidental to and supportive of speech may run afoul of the First Amendment. The decision below also conflicts with recent decisions of at least two other courts of appeals. The majority rule is that information collected, compiled and used for commercial solicitation is not categorically excluded from First Amendment scrutiny—it is, in fact, integral to and inseparable from the ultimate

commercial solicitation, and fits comfortably within the core notion of commercial speech.

The First Circuit's decision to the contrary poses a serious threat to the dissemination of a broad array of important information. By ruling that the affected information falls entirely outside the purview of the First Amendment, the court below has announced a novel proposition that is at odds with the fundamental role that information plays in our free-enterprise economy.

ARGUMENT

IT IS CRITICALLY IMPORTANT THAT THE COURT GRANT CERTIORARI AND CORRECT THE ERRONEOUS HOLDING THAT THE NEW HAMPSHIRE STATUTE IS NOT A REGULATION OF SPEECH THAT MUST BE ANALYZED UNDER THE FIRST AMENDMENT

The majority decision below acknowledges, as it must, that "pure informational data can qualify for First Amendment protection." Pet. App. 19 (citing *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976)). Things like lists of pharmaceutical products and prices, though "merely report[ing] fact[s]," have long been protected as speech under the First Amendment. *Id.* The majority decision below nevertheless holds that the Laws' ban on certain commercial transfers of informational products incorporating prescriber-identified drug data does not amount to a limitation of speech covered by the First Amendment at all. Pet. App. 26.

In reaching that conclusion, the court below asserted that the New Hampshire Law "principally regulate[s] conduct because those provisions serve only to restrict the ability of data miners to aggregate, compile, and transfer information destined for narrowly defined commercial ends." *Id.* at 22. Thus, the court reasoned, "this is a situation in which information itself has become a commodity," *id.* at 23, and, as such, the court concluded, treating it differently than some other product—"say, beef jerky"—would "stretch[] the fabric of the First Amendment beyond any rational measure." *Id.* The court noted that the "certain information exchanges . . . foreclosed by the . . . Law" are not of the type "valued by the Supreme Court's First Amendment jurisprudence but, rather, are exchanges undertaken to increase one party's bargaining power in negotiations." *Id.* at 26. Accordingly the court concluded that the "challenged portions of the . . . Law fall outside the compass of the First Amendment," and are thus entitled only to rational basis review. *Id.*

This conclusion is obviously incorrect for a number of reasons.

A. Contrary To The Court Below, The Aggregation, Organization, Compilation And Sale Of Truthful Information To Be Used For Commercial Purposes Is Protected Speech And Has Nothing In Common With Unprotected Forms Of Speech, Such As Obscenity, Harassment, Or Fighting Words

The New Hampshire Law proscribes the "transfer" of data from companies like Source

Healthcare Analytics to individuals and companies who will use that data for a specific purpose. *See* Prescription Restraint Law, 2006 N.H. Laws 328 (codified at N.H. REV. STAT. ANN. §§ 318:47-f, 318:47-g, 318-B:12, IV) (making unlawful the “license[], transfer[], use[] or [sale]” of prescriber-identified drug data for “any commercial purpose”). This “transfer” of information from one person to another, with the expectation that the information will be used by the recipient to inform and assist him in his business dealings, is near the heart of any reasonable concept of protected speech.

Amicus's products that fall within the purview of New Hampshire's statute result from a complex process of data collection, analysis and presentation in a form suited to the needs of particular end users. The fact that these products are sold as “a commodity,” Pet. App. 23, does not in any way suggest that they fall outside the reach of the First Amendment. Books, newspapers, magazines and website access are all forms of information sold as “a commodity,” and certainly no State could regulate the transfer of these items without any First Amendment scrutiny. *See Riley v. Nat'l Fed'n of Blind of N.C., Inc.*, 487 U.S. 781, 801 (1988) (“It is well-settled that a speaker's rights are not lost merely because compensation is received; a speaker is no less a speaker because he or she is paid to speak.”). Far from “stretch[ing] the fabric of the First Amendment beyond any rational measure,” Pet. App. 23, providing protection to information that is sold is a core concern of the Constitution.

To support its conclusion that the First Amendment is entirely inapplicable, the court further noted that “to the extent that the challenged portions impinge at all upon speech, that speech is of scant societal value.” *Id.* at 22. It placed the prescriber-identified drug data in the same “integument” as communications in restraint of trade, in furtherance of crimes, illegal labor activities, harassment, and fighting words, which categorically receive no constitutional protection because of their “nugatory informational value.” *Id.* (citing cases).

This Court has sometimes said that these latter categories of expression are “not within the area of constitutionally protected speech,” *Roth v. United States*, 354 U.S. 476, 483 (1957); *Chaplinsky v. New Hampshire*, 315 U.S. 568, 571-72 (1942); or that the “protection of the First Amendment does not extend” to them, *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 504 (1984); *Sable Commc’ns of Cal., Inc. v. FCC*, 492 U.S. 115, 124 (1989). Such statements must be taken in context, however, and “are no more literally true than is the occasionally repeated shorthand characterizing obscenity ‘as not being speech at all.’” *R.A.V. v. City of St. Paul*, 505 U.S. 377, 383 (1992) (citation omitted). “What they mean is that these areas of speech can, consistently with the First Amendment, be regulated *because of their constitutionally proscribable content* (obscenity, defamation, etc.)—not that they are categories of speech entirely invisible to the Constitution . . . [and] they may be made the vehicles for content discrimination.” *Id.* at 383-84 (emphasis in original).

Thus, the fact that the categories of proscribable speech listed by the majority decision below can be regulated consistent with the First Amendment, *see* Pet. App. 20, does not mean that they cease to be speech within the meaning of the First Amendment. For instance, yelling fire in a crowded building, while certainly a form of speech in the everyday sense of the word, is proscribable because it carries such a great inherent risk of harmful consequences while having no apparent redeeming First Amendment value. *See Schenck v. United States*, 249 U.S. 47, 51-52 (1919) (Holmes, J.). Yet, "[t]he shout of 'Fire!' is not less speech in the Holmes instance than the shout of 'Fire!' from the mouth of an actor on the stage of the same theater, spoken as but a word in a play. It is futile to argue that an appropriately tailored law that punishes any or all of these utterances does not abridge speech." William W. Van Alstyne, *A Graphic Review of the Free Speech Clause*, 70 CAL. L. REV. 107, 114 (1982) (footnotes omitted). Most certainly, one cannot justify any such restrictions on the ground offered by the Court below—that they "principally regulate conduct." Pet. App. 22.

Regulations flatly barring certain forms of speech are proper not because the proscribed act is something other than speech, but rather because the expression is so inherently harmful and lacking in redeeming value that the courts have uniformly upheld its prohibition notwithstanding that it involves a form of expression. This is why speech aimed at illegally colluding on the price of products may be regulated consistent with the First

Amendment. *See NAACP v. Claiborne Hardware Co.*, 458 U.S. 886, 912 (1982) (recognizing the "strong governmental interest" in regulating anticompetitive conduct, "even though such regulation may have an incidental effect on rights of speech and association"). For much the same reasons, racist, discriminatory, or sexually harassing speech escape First Amendment scrutiny. The fact that a supervisor's statement "sleep with me or you're fired" is not protected by the First Amendment does not mean that it is not actually speech. Rather, it is proscribable under this Court's case law because it expresses a verbal threat of illegal discrimination, *see* 42 U.S.C. § 2000e-2(a)(1), while carrying no redeeming content or message. *See NLRB v. Gissel Packing Co.*, 395 U.S. 575, 618 (1969) (holding that employer's "threat of retaliation" on basis of union membership was "without the protection of the First Amendment").

The prescriber-linked data whose commercial distribution is prohibited by the Law bears no resemblance to obscenity, discriminatory threats and proposals of collusive, anticompetitive behavior. As an aggregator, organizer, and publisher of such information, which people in diverse occupations need and use for business, governmental, and other legitimate and valuable purposes, but would have great difficulty accessing in the absence of its services, *Amicus* submits that the decision below is obviously incorrect. It holds without basis that, while the raw data can qualify for First Amendment protection, Pet. App. 19, and while the transferees' ultimate marketing efforts using that data are no

doubt protected speech, see *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 366-67 (2002), the transfer of that data from its raw form to the end user is of such "nugatory informational value" and "scant societal value" that it does not even trigger First Amendment consideration. Pet. App. 22, 26.

The "societal interests in broad access to complete and accurate commercial information" is precisely the interest that the "First Amendment coverage of commercial speech is designed to safeguard." *Edenfield v. Fane*, 507 U.S. 761, 766 (1993) (citing *Va. Bd. of Pharm.*, 425 U.S. at 762-65); *Cent. Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n*, 447 U.S. 557, 561-62 (1980); see also *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985) ("the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides"). For this reason, the government cannot proscribe the most efficient means of disseminating specific information about what is being sold, by whom and at what price, even though the underlying information itself—if diligently sought out by interested persons—remains publicly available. See *Linmark Assocs., Inc. v. Twp. of Willingboro*, 431 U.S. 85, 93, 96-97 (1977) (striking down a law that forbid the posting of realty "For Sale" signs in front yards because signs are the most "effective media" to reach potential buyers with "vital . . . information [on] sales activity"); *Edenfield*, 507 U.S. at 766 (striking down a law that forbid the "direct and spontaneous communication between buyer and seller" which is more effective and

informative than alternative means of communication). The value of the information at issue here is demonstrated by the fact that there is a substantial market to which *Amicus* and Petitioners respond by tailoring products for particular uses.³

"The general rule is that the speaker and the audience, not the government, assess the value of the information presented." 507 U.S. at 767. "People will perceive their own best interests only if they are well enough informed, and the best means to that end is to open the channels of communication rather than to close them." *Linmark*, 431 U.S. at 97

³ In this and similar situations, "you have both somebody who wants to speak, . . . someone who affirmatively wants to hear what [the speaker] has to say," and the government saying "no, the two of you can't do this." Tr. of Argument at 48, *Citizens United v. Fed. Election Comm'n*, March 24, 2009, 2009 WL 760811, at *48 (No. 08-205). This "kind of censorship . . . raise[s] grave First Amendment concerns," *Thornburgh v. Abbott*, 490 U.S. 401, 407 (1989), as it dangerously proscribes what specific, willing listeners may hear, read and ultimately act upon. The First Amendment has long protected a willing listener's "right to receive information and ideas"—regardless of what the state may think of those ideas, *Stanley v. Georgia*, 394 U.S. 557, 564 (1969)—even where the judicially enforceable free speech right belongs to the speaker. See, e.g., *Thomas v. Collins*, 323 U.S. 516, 534 (1945) (where "there was restriction upon Thomas' right to speak," there was also a restriction upon the "rights of the workers to hear what he had to say"); *Procunier v. Martinez*, 416 U.S. 396, 408 (1974), *overruled in part by Thornburgh*, 490 U.S. 401 ("Both parties to the correspondence have an interest in securing that . . . the letter is read by the addressee, . . . and censorship of the communication between them necessarily impinges on the interest of each.").

(quoting *Va. Bd. of Pharm.*, 425 U.S. at 770). Here, the communication of product information by a pharmaceutical representative to a doctor permits the doctor to make informed, economic decisions about what drugs to prescribe to his or her patients. So long as it is truthful, this communication falls within the ambit of the First Amendment. In the same way, the communication of prescriber-identified information from *Amicus* to the pharmaceutical company for use by its representatives is plainly speech whose restriction demands First Amendment scrutiny.

B. The New Hampshire Law Is No Less A Restriction Of Speech Simply Because It Works Indirectly To Curtail Downstream Speech Through A Ban On Upstream Transfers Of Information That Make The Latter Speech Possible

Wanting to constrict the ultimate dialogue between the sales representative and the doctor, but recognizing the constitutional obstacles in doing so, New Hampshire made an end-run around the First Amendment by restricting the penultimate communication between information services providers, like *Amicus* and Petitioners, and the pharmaceutical company. As the dissent below pointed out, "[t]he State has attempted to insulate this expression-based [regulation] from First Amendment scrutiny by directing its legislation to an earlier step in the communicative process." Pet. App. 88 (Lipez, J., dissenting). The State has even conceded that the Law seeks to "strike at the source" of the message, rather than restrict the message

itself. *Id.* at 87 (citing the New Hampshire Attorney General's characterization of the Law before the trial court).

By removing the predicate information that informs the representative's speech from the protection of the First Amendment, the majority decision below conflicts with a long and unbroken line of this Court's precedent.

Starting with *Grosjean v. American Press Co.*, 297 U.S. 233 (1936), this Court has held that governmental impairment of activities incidental to and supportive of speech may run afoul of the First Amendment. In that case, the State of Louisiana imposed a license tax of 2% of the gross receipts from the sale of advertising on all newspapers with a weekly circulation above 20,000. After noting that the tax curtailed the flow of information, *id.* at 250-51, the Court held the tax invalid as an abridgment of the freedom of the press. "[The tax] is bad because . . . it is seen to be a deliberate and calculated device in the guise of a tax to limit the circulation of information." *Id.* at 250. Later, this Court clarified that even where there is no evidence of impermissible legislative motive, placing a burden selectively on a critical component of actual speech amounts to a burden on the speech itself. *Minneapolis Star & Tribune Co. v. Minn. Comm'r of Revenue*, 460 U.S. 575, 581 (1983) (a tax on newsprint and ink consumed in the production of publications was unconstitutional because it negatively impacted speech); see also *City of Cincinnati v. Discovery*

Network, Inc., 507 U.S. 410, 426-29 (1993); *Lakewood v. Plain Dealer Publ'g Co.*, 486 U.S. 750, 757 (1988).

It is not meaningful to say that a person has the "freedom of speech" without having the ability to put ideas together and combine facts and ideas in order to formulate his message. Thus, the generation, assembly, compilation and analysis of information, and its communication to interested users, lie at the core of what the First Amendment protects. *See Va. Bd. of Pharm.*, 425 U.S. at 764.⁴

Thus, the State of New Hampshire cannot "skirt the Constitution's requirements" by "directing its legislation to an earlier step in the communicative process." Pet. App. 88 (Lipez, J., dissenting). It

⁴ The Supreme Court has also recognized explicitly the legitimacy of compilations and expressions that borrow, collect, and juxtapose the expressions and ideas of others to present a new message or idea: "[A] private speaker does not forfeit constitutional protection simply by combining multifarious voices, or by failing to edit their themes to isolate an exact message as the exclusive subject matter of the speech. Nor, under our precedent, does First Amendment protection require a speaker to generate, as an original matter, each item featured in the communication." *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Group*, 515 U.S. 557, 569-70 (1995). *See Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 636 (1994) ("Cable programmers and cable operators engage in and transmit speech, and they are entitled to the protection of the . . . First Amendment. Through 'original programming or by exercising editorial discretion over which stations or programs to include in its repertoire,' cable programmers and operators 'see[k] to communicate messages on a wide variety of topics and in a wide variety of formats.'") (citations omitted; brackets in original).

cannot target the content of the ultimate speech—here the representative-physician dialogue—simply by imposing restrictions on an earlier transfer of information on which the representatives rely. The fact that no direct restraint or punishment is imposed upon the ultimate speech by sales representatives “does not determine the free speech question.” *Am. Commc’ns Ass’n, C.I.O. v. Douds*, 339 U.S. 382, 402 (1950). The earlier transfer of truthful information is speech under the First Amendment in its own right, precisely because it has the potential to inform the thoughts and actions of others.

C. The Decision Below Conflicts With Decisions Of Other Circuits In Reasoning That There Is No Impact On Speech Because The Ban On Information Transfer Is Limited To Particular Commercial Uses

The decision below also conflicts with recent decisions of at least two other courts of appeals, in categorically excluding from First Amendment scrutiny a ban on the transfer of information, on the ground that it is narrowly targeted on transfers for defined commercial purposes.

In *U.S. West, Inc. v. FCC*, 182 F.3d 1224 (10th Cir. 1999), the government argued that FCC regulations barring telephone companies from using their own customer information for targeted marketing purposes did not infringe commercial speech. In its view, “the [regulations] only prohibit [the company] from using [the information] to target customers and do not prevent petitioner from

communicating with its customers or limit anything that it might say to them." *Id.* at 1232.

The Tenth Circuit in *U.S. West* rejected this argument because use of the proscribed data was "integral to and inseparable from the ultimate commercial solicitation," which is itself a protected form of speech. *Id.* at 1233 n.4. Because the proscribed use of the customer information itself "facilitate[d] the marketing of telecommunications services to individual customers," the Tenth Circuit held that use was "properly categorized as commercial speech." *Id.* The court thus examined the regulations under the *Central Hudson* test for commercial speech, and found the restriction invalid. *Id.* at 1233-35.

The majority decision in this case adopted precisely the line of reasoning rejected by the Tenth Circuit. In the view of the First Circuit, because Petitioners could "still gather, . . . publish, transfer and sell this information to whomever they choose *so long as that person does not use the information for detailing* . . . the restriction here is on the conduct (detailing) and not on the information with which the conduct is carried out." Pet. App. 24 (emphasis and parenthesis in original). The court thus wholly rejected the analysis found dispositive in *U.S. West*, that the restricted information transfer was "integral to and inseparable from the ultimate commercial solicitation" 182 F.3d at 1233 n.4.

Similarly, in *United Reporting Publishing Corp. v. California Highway Patrol*, 146 F.3d 1133 (9th Cir.), *rev'd on other grounds*, 528 U.S. 32 (1999), a

California law prohibited the release of arrestee-identified information to people who intended to use it for commercial purposes. Like Petitioners and *Amicus* here, United Publishing was in the business of collecting, organizing and selling data to commercial entities, and they sold arrestee-identifiable information to businesses who would then solicit the arrestees to purchase their services (anything from legal services to drug and alcohol counselors to driving schools). In striking down the statute on First Amendment grounds, the Ninth Circuit held that the data was, in fact, "commercial speech":

United Reporting sells arrestee information to clients; nothing more. Its speech can be reduced to, "I [United Reporting] will sell you [client] the X [names and addresses of arrestees] at the Y price." This is a pure economic transaction, comfortably within the "core notion" of commercial speech.

Id. at 1137 (citing *Va. Bd. of Pharm.*, 425 U.S. at 762) (internal citations omitted). The arrestee information, like the prescriber-identifiable drug data here, could be characterized as a "commodity," but the court held it nonetheless deserved the protection of the First Amendment. The Ninth Circuit then applied the *Central Hudson* test and struck down the statute.⁵

⁵ This Court's decision to reverse the Ninth Circuit in *United Reporting Publishing* was not inconsistent with its holding that the information was "speech" within the protection

Like the restriction on the sale of arrestee-identified information in *United Reporting Publishing*, New Hampshire's restriction on the sale of prescriber-identified data impinges upon a "pure economic transaction" for the sale of truthful, factual information, and thus falls "comfortably within the core notion of commercial speech."

The decision below is thus in conflict with decisions of the Ninth and Tenth Circuits.

(continued...)

of the First Amendment. See *Los Angeles Police Dep't v. United Reporting Publ'g Co.*, 528 U.S. 32 (1999) (holding that respondent could not assert a facial challenge to the statute where it could not first gain access to the information it wished to convey as speech). Indeed, a majority of this Court in *United Reporting Publishing* appeared to agree that, once the arrestee-identified information is in the speaker's possession, the First Amendment would presumably protect the speaker's ability to transmit that information to another person. See *id.* at 40 ("This is not a case in which the government is prohibiting a speaker from conveying information that the speaker already possesses") (citing *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995); *id.* at 42 ("Anyone who [possesses] arrestee address information . . . is free to use that information as she sees fit, . . . and [the law being challenged] would indeed be a speech restriction if it . . . prohibited people from using that information to speak to or about arrestees.") (Ginsburg, J., concurring).

D. The First Circuit's "No Speech" Ruling Poses A Serious Threat To The Dissemination Of A Broad Array Of Important Information

We live in a society that thrives on—and regularly puts to myriad commercial and personal uses—an enormous quantity of information of all types. This information is often distributed by the speaker for profit, with an active marketplace of readers and listeners willing to pay for information that is useful in their own commercial ventures. Increasingly this information is served up with the assistance of the internet and other media of mass communications by people and businesses—and to people and businesses—engaged in a nearly infinite range of endeavors.

This information plays an important role in our "predominantly free enterprise economy." *Va. Bd. of Pharm.*, 425 U.S. at 765. This Court has acknowledged that "the allocation of our resources in large measure will be made through numerous private economic decisions," and that "[i]t is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. . . . [through] the free flow of commercial information." *Id.* This is precisely why commercial actors have a right "to acquire useful knowledge," *Bd. of Regents v. Roth*, 408 U.S. 564, 572 (1972) (internal quotation marks omitted), and, once that information is at hand, they then have a right to convey it subject to the strictures of the First Amendment, *see Rubin*, 514 U.S. at 483-86 (analyzing under *Central Hudson* a statute restricting the conveyance of information in a

speaker's possession). By ruling that prescriber-linked prescription data sold for commercial purposes falls entirely outside the purview of the First Amendment, the court below has announced a novel proposition, at odds with the "natural right of the members of an organized society . . . to impart and acquire information about their common interests." *Grosjean*, 297 U.S. at 243.

CONCLUSION

For all of the foregoing reasons, *Amicus* Source Healthcare Analytics urges the Court to grant the Petition.

Respectfully submitted,

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**In The
Supreme Court of the United States**

IMS HEALTH, INC. AND VERISPAN LLC,

Petitioners,

v.

KELLY A. AYOTTE, AS ATTORNEY GENERAL
OF THE STATE OF NEW HAMPSHIRE,

Respondent.

**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The First Circuit**

**BRIEF OF THE STATE OF VERMONT
AS AMICUS CURIAE IN SUPPORT OF
RESPONDENT AND IN OPPOSITION
TO THE PETITION FOR WRIT OF CERTIORARI**

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**INTEREST OF AMICUS CURIAE
STATE OF VERMONT¹**

Vermont, like New Hampshire, has chosen to restrict the use of prescriber-identifiable data (data taken from patient prescription records) for marketing prescription drugs. Vermont's law, passed in 2007, is similar in purpose to the New Hampshire statute upheld by the First Circuit. *See* Vt. Stat. Ann. tit. 18, § 4631. As with New Hampshire, Vermont's law has a "limited scope" that does not restrict any "message disseminated to the public at large." Pet. App. 126, 131 (Lipez, J., concurring). While New Hampshire decided to prohibit the use of prescriber-identifiable data for marketing prescription drugs, Vermont created a process for doctors to decide whether or not their prescription information may be used for marketing purposes. Absent consent, pharmaceutical companies may not use the data for marketing drugs. Vermont's law was upheld by a federal district court following a five-day bench trial. *IMS v. Sorrell*, No. 1:07-cv-188, 2009 WL 1098474 (D. Vt. Apr. 23, 2009). An appeal is now pending in the Second Circuit.²

Because of this pending litigation, Vermont has taken the unusual step of appearing as amicus curiae

¹ As required by Supreme Court Rule 37.2, counsel of record received timely notice of Vermont's intent to file this amicus brief. Because the brief is filed by Vermont's Attorney General, Vermont does not need permission to file. *See* Supreme Court Rule 37.4.

² The appeal was docketed May 4, 2009.

in opposition to this petition for certiorari. Petitioners' challenge to New Hampshire's data mining law was expedited and trial was held after only a short period of discovery. Vermont's law had a delayed effective date, and that allowed Vermont to conduct substantially more discovery and to prepare a more detailed case for trial. For example, Vermont elicited discovery from pharmaceutical companies about the covert use of prescriber-identifiable data in drug marketing; obtained company documents from the data mining industry; and presented expert testimony showing that these laws will not just help reduce health care costs but also will reduce unnecessary risk to patients and promote public health. *Compare id.* at *13 (finding evidence supports State's interest in protecting public health) *with* Pet. App. 106 (Lipez, J., concurring) (describing New Hampshire's record on this issue as "undeveloped").

For these reasons, Vermont believes that the pending case presents a poor vehicle for this Court to review the constitutionality of restrictions on the use of prescriber-identifiable data. With no split of authority calling for the Court's intervention, the Court should not reach out to decide this case and short-circuit development of the issues in the lower courts. Moreover, if the Court believes review of this issue is necessary – and it may not be, if no conflict develops in the Courts of Appeal – that review should not be based upon a record compiled in an expedited proceeding. Vermont thus submits this brief to aid the

Court in its consideration of the petition for certiorari.

STATEMENT OF THE CASE

Pharmaceutical companies spend billions of dollars each year marketing drugs directly to doctors. *E.g.*, Pet. App. 31; *Sorrell*, 2009 WL 1098474, at *1. These marketing efforts are limited to expensive, brand-name drugs that retain patent protection (that is, most marketing efforts stop once generic versions of a drug become available). Pet. App. 6, 163. There is no question but that these sophisticated, expensive marketing campaigns succeed in influencing doctors to prescribe the drugs being marketed. The First Circuit reached this conclusion, as did the District Court in Vermont. *E.g.*, Pet. App. 30-31; *Sorrell*, 2009 WL 1098474, at *11. These lower court decisions are firmly grounded in empirical evidence, including a substantial body of peer-reviewed research showing that doctors' prescribing decisions are influenced by marketing campaigns. Pet. App. 31-32; *id.* at 109-12, 122 (Lipez, J., concurring) (discussing research); *Sorrell*, 2009 WL 1098474, at *11 ("Research shows doctors are influenced by the marketing efforts of pharmaceutical companies."). In Vermont's trial, three respected scientists testified about the nature of this influence and the studies that document it. A recent report by the Institute of Medicine likewise shows that the medical profession recognizes the influence of marketing. The report recommends that

institutions and physicians adopt sharp new limits on interactions between pharmaceutical sales representatives and doctors (as well as medical students and residents).³

A few years ago, press accounts began to highlight what was then a little-known fact about drug marketing. *E.g.*, Pet. App. 32 (citing 2003 Boston Globe article). Coincident with a sharp rise in spending on pharmaceutical marketing, pharmaceutical companies also began using a new marketing tool: data culled from patients' prescriptions records that revealed the prescribing practices of individual doctors. *Sorrell*, 2009 WL 1098474, at *2. Data mining companies, like the petitioners in this case, obtain this data by buying patients' prescription records from pharmacies. The patient's name is encrypted, and some other identifying information is removed, but essentially, data mining companies purchase detailed health care records from pharmacies. An individual prescription record shows, for example, that Dr. Jane Jones prescribed Lipitor to

³ Committee on Conflict of Interest in Medical Research, Education, and Practice, Institute of Medicine, *Conflict of Interest in Medical Research, Education, and Practice* 5-4, 5-6 to 5-14, 5-28 to 5-30, 6-7 to 6-8, 6-15 to 6-17 (Bernard Lo & Marilyn J. Field, eds., 2009) (presently available in uncorrected proofs at http://www.nap.edu/catalog.php?record_id=12598). As one example relating to medical education, the report observes that "the literature suggests that academic medicine and the public have reason to be concerned about the easy access of sales representatives to medical students, residents, and faculty." *Id.* at 5-9.

Patient X, a 50-year-old man who lives in central Vermont, and who had the prescription filled on June 1, 2009 at the Rite Aid pharmacy in Montpelier, Vermont. *See Sorrell*, 2009 WL 1098474, at *1 (describing data purchased from prescription records). By combining prescription records from most pharmacies, the data mining companies can track how often Dr. Jones prescribes Lipitor, how often she prescribes other cholesterol-reducing drugs, what combinations of drugs she uses, and whether she prescribes a particular drug as first-line treatment or as an alternative after other treatments fail. The evidence in Vermont's trial showed that patient identity is encrypted in a way that allows data mining companies to track the drugs prescribed to a particular, though anonymous, patient and identify the doctors who write the prescriptions.

As data mining companies emphasized to pharmaceutical companies, using this data to market drugs to doctors would increase sales and profits, and allow the companies to "reap[] big returns." But pharmaceutical companies took pains not to explain this new marketing practice to doctors. Sales representatives were trained not to discuss the data with doctors and to leave their laptop computers (loaded with detailed spreadsheets tracking doctors in their territory) outside doctors' offices. Neither data mining companies nor pharmaceutical companies made any effort to get the consent of patients or doctors before using their information as a marketing tool. For the most part, patients and

doctors did not even know that health care records were being sold and used in this way. *E.g.*, Pet. App. 23 n.6; *Sorrell*, 2009 WL 1098474, at *12 n.15.

Beginning in 2006, three state legislatures have taken a close look at the practice of using prescriber-identifiable data from prescription records for marketing prescription drugs. After investigation and deliberation, these three legislatures in Maine, New Hampshire, and Vermont decided to regulate the practice to protect privacy, contain unnecessary health care spending, and protect the public health. The narrow question posed by this case, and similar cases still pending in the lower courts, is whether states have authority, consistent with the First Amendment, to regulate the sale and commercial use of this data that is drawn from nonpublic patient health care records.

ARGUMENT

Petitioners have not advanced persuasive grounds for the Court to grant the petition for certiorari. The Court does not typically grant review in the first case to raise a particular issue, especially when, as here, other similar cases are pending in the lower courts. There are good reasons to adhere to that practice and deny the petition in this case. The expedited trial court proceeding and certain procedural issues discussed below cloud any potential First Amendment review. Just as importantly, the

Courts of Appeal have only begun to consider the First Amendment arguments asserted by petitioners. The Court should not reach out to decide the question at this early stage. Indeed, absent a conflict in the lower courts, this Court's review may not be required at all.

New Hampshire's brief in opposition fully addresses the principal points raised by the petition and shows why the conflicts asserted by petitioners either do not exist or are not relevant to the petition for certiorari. Vermont seeks to add to this conversation by showing that this case is a poor vehicle for the Court to consider whether restrictions on the use of prescriber-identifiable data satisfy the *Central Hudson* standard for commercial speech. See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). The First Circuit applied *Central Hudson* as a separate and fully dispositive ground for upholding New Hampshire's law, and petitioners ask this Court to review that fact-intensive holding. See Pet. 24-37. The Court should not do so. To begin with, this is not only the first case to raise this issue, it is also a facial challenge that was expedited in the trial court. As a result, New Hampshire did not have a full opportunity to develop a factual record and the decision below reflects uncertainty about petitioners' standing and the scope of New Hampshire's law. Second, the decision by the District Court in Vermont's case confirms that the First Circuit's application of *Central Hudson* to these facts is unremarkable. Assuming *Central Hudson* review is

even required,⁴ restrictions on the use of prescriber-identifiable data readily satisfy that standard. Other courts have likewise upheld limited restrictions on the use or disclosure of data; nothing about the First Circuit's ruling on this point warrants Supreme Court review.

I. This case is a poor vehicle for reviewing the fact-intensive application of *Central Hudson* to restrictions on the use of prescriber-identifiable data.

New Hampshire was the first state to restrict the use of prescriber-identifiable data in marketing prescription drugs. Petitioners filed suit in July 2006, shortly after New Hampshire's law became effective. The District Court expedited the case and it went quickly to trial six months later, in January 2007. *See* Pet. App. 10-11. The record shows that the parties conducted minimal discovery. New Hampshire relied primarily upon the legislative record together with expert testimony about pharmaceutical marketing practices. Vermont agrees with New Hampshire and the First Circuit that this record is certainly sufficient to support the law's constitutionality under

⁴ Vermont agrees with the First Circuit that New Hampshire's law regulates commercial conduct, not speech protected by the First Amendment. But as Vermont has consistently argued in its own case, even if the *Central Hudson* standard applies, these narrowly-tailored restrictions on the use of prescriber-identifiable data are constitutional.

Central Hudson. See Pet. App. 41; *id.* at 122 (Lipez, J., concurring) (noting the “extent of [New Hampshire’s] empirical and anecdotal evidence”). But the record does not provide a complete picture of the ways in which pharmaceutical companies rely upon the covert use of data mining to market their products to doctors. That outcome is not surprising: petitioners brought a facial challenge to New Hampshire’s statute, the case was tried very quickly, and no pharmaceutical company participated in the lawsuit.

These factors – petitioners’ facial challenge, the expedited proceeding, and the lack of a proper plaintiff – all point toward the same conclusion: this is not a particularly good case for the Court to grant review.

A. Facial challenges are disfavored, even in First Amendment cases.

Petitioners chose to bring a facial challenge to New Hampshire’s law. See Pet. App. 45. “Facial challenges are disfavored,” *Washington State Grange v. Washington State Republican Party*, 128 S. Ct. 1184, 1191 (2008), and the difficulty of adjudicating a facial challenge, see *id.* at 1190-91, is one reason not to grant review in this case. Petitioners may argue that a facial challenge is appropriate because they claim that New Hampshire’s law restricts their speech rights. *Cf. id.* at 1191 n.6. The question at this point, however, is not whether petitioners’ facial challenge is justiciable, but whether the case is a

suitable vehicle for this Court's review. Facial challenges are disfavored in part because, when a statute has not been implemented or enforced, the Court may not have the best record possible to assess the statute's constitutionality. *See id.* at 1190-91; *see also Crawford v. Marion County Election Bd.*, 128 S. Ct. 1610, 1622-23 (2008) (Stevens, J., joined by Roberts, C.J. and Kennedy, J.). The facts may not be developed fully and questions may remain about the statute's interpretation that can only be resolved by the state courts. *See Washington State Grange*, 128 S. Ct. at 1190-91. As explained further below, these concerns are present here. Had petitioners' claims arisen in the context of an enforcement action brought by New Hampshire's Attorney General, the courts could have undertaken review with the benefit of a precise factual application. And the state courts could have resolved any questions about the statute's meaning. That did not happen, however, and this Court should accordingly hesitate to entertain petitioners' request to invalidate New Hampshire's statute on its face. *See Ayotte v. Planned Parenthood of Northern New England*, 546 U.S. 320, 329 (2006) ("ruling of unconstitutionality frustrates the intent of the elected representatives of the people").

B. New Hampshire's expedited proceeding foreclosed discovery of additional relevant information.

In reaching its final decision upholding Vermont's law, the District Court in Vermont observed that the

parties presented “testimony from numerous witnesses and introduced reams of exhibits.” *Sorrell*, 2009 WL 1098474, at *4. Vermont’s legislative record, introduced at trial, comprises hundreds of pages of expert testimony, news reports, journal articles, and testimony from Vermont doctors. The trial record includes expert opinion testimony about the influence of marketing on doctors and its impact on the doctor-patient relationship; the unjustified over-prescription of expensive new drugs; the risk to patients from unnecessary prescription of new drugs with unknown risks; and the potential cost savings if prescribing practices shift even slightly in favor of generic drugs. Importantly, Vermont’s record also includes industry documents obtained in discovery from data mining and pharmaceutical companies. While New Hampshire presented a strong body of evidence, sufficient for all three judges below to uphold New Hampshire’s law, the expedited proceeding in New Hampshire foreclosed that state’s opportunity to conduct additional discovery and present additional evidence.

Vermont cannot summarize its record here, nor would it be appropriate to do so. Discussion of a few points, however, is helpful to illustrate the ways in which Vermont’s record expands upon – and fully supports – the First Circuit’s *Central Hudson* analysis.

1. Vermont’s record contained substantially more detail about the State’s interest in protecting the health and safety of its residents. Vermont’s experts provided detailed testimony about the

uncertain risks posed by new drugs, and the need to avoid over-prescription of those drugs before their use and risks are fully understood. The District Court's opinion recounts some of this evidence about drugs like Baycol and Vioxx, which were widely and unnecessarily over-prescribed before they were withdrawn from the market for safety reasons. *Sorrell*, 2009 WL 1098474, at *13. One of the plaintiffs' key witnesses – the “distinguished cardiologist” who also testified for petitioners in New Hampshire, Pet. App. 32 – provided important testimony supporting Vermont on this precise point. *Sorrell*, 2009 WL 1098474, at *13 (citing testimony of Dr. Wharton). The District Court found this evidence persuasive and concluded that Vermont's law substantially advances the State's interest in protecting patient health as well as its interest in controlling health care costs. *Id.*

The First Circuit, on the other hand, did not consider the State's interest in promoting public health. Pet. App. 28. In his separate opinion, Judge Lipez opined that New Hampshire's record on this point was “undeveloped” and “inadequate” under *Central Hudson*. Pet. App. 106 (Lipez, J., concurring). The District Court's ruling in Vermont shows that public health is affected by the use of prescriber-identifiable data for marketing, and should be given full consideration under *Central Hudson*.

2. Vermont's direct evidence about pharmaceutical marketing practices, particularly evidence obtained in discovery from industry sources, provides

strong support for the States' *Central Hudson* arguments. As one example, petitioners here promote pharmaceutical detailing using prescriber-identifiable data as an "exchange of valuable, truthful information between doctors and pharmaceutical companies." Pet. 23-24. When these same data mining companies promote the use of prescriber-identifiable data to pharmaceutical companies, however, the message sounds quite different. In fact, the message sounds much like what New Hampshire and Vermont say: that using prescriber-identifiable data in marketing allows drug companies to substantially increase drug sales and profits. IMS executives expressly describe the aim of purchasing prescriber-identifiable data as "reaping big returns." They describe one company increasing its market share by 86%. *Sorrell*, 2009 WL 1098474, at *11. Promotional materials from another data mining company explain that sales representatives use prescriber-identifiable data to gain access to the "most valuable prescribers," which in turn leads to more prescriptions, increased revenue, and profits. As for the supposed "exchange of valuable, truthful information," an IMS executive expressed a different view in a promotional industry article. He pointed out that prescriber-identifiable data answers the two most important questions for pharmaceutical sales representatives: "how much am I getting paid" and "what do I need to do to make more money." Another IMS brochure sums up the point in unmistakable terms. Prescriber-identifiable data lets companies "maximize the revenue per call and the scripts per detail."

Along with information from data mining companies, Vermont obtained discovery from numerous pharmaceutical companies and used the results to help prove its case at trial. These internal pharmaceutical company documents rebut both petitioners' claims and the assertions made in PhRMA's amicus brief in support of the petition. Like petitioners, PhRMA tries to convince the Court that restricting the use of prescriber-identifiable data will make detailing "less informative." PhRMA Amicus Br. 11. The District Court in Vermont's case flatly rejected this contention, and concluded that prescriber-identifiable data "does not add" to the "purported educational value" of detailing. *Sorrell*, 2009 WL 1098474, at *11.⁵ The court's finding on this point is fully supported by industry documents that show how companies use prescriber-identifiable data for marketing. Some examples from these documents contradict PhRMA's assertions that the data is used to "facilitate discussions" and "provide doctors the most useful scientific information." PhRMA Br. 10.

⁵ The District Court likewise rejected PhRMA's claim that using the data makes detailing more efficient because it allows sales representatives to determine which doctors may be interested in using a drug. The District Court found that sales representatives record and track numerous details about the doctors they visit, including birthdays and favorite sports teams, and thus can easily track a doctor's specialty areas. *Sorrell*, 2009 WL 1098474, at *12.

- Managers are trained to use the data to provide feedback to sales representatives, with suggested statements like: "These are really important doctors in your territory, but they are really dragging down your share. If you move 10 of these doctors by 5 percentage points, you will hit your [sales] goal easily."
- Sales representatives use prescriber-identifiable data in a "payout calculator." The representative plugs in the desired salary or bonus and the calculator shows the volume of prescriptions or market share needed to achieve that goal.
- Sales representatives get regular email "alerts" telling them things like which prescribers are "underperforming" (that is, not writing enough prescriptions).
- Companies train sales representatives to use prescriber-identifiable data to target doctors based on sales and market share. As one company explains, sales representatives should use the data to "[l]ocate Top Potential Physicians" that "can help move share." After sorting their list of physicians, sales representatives should "delete" physicians who do not make the "market share cutoff," leaving on the list "only those top physicians that can help move share."

These materials and others seriously undermine claims both about the benefits of marketing using

prescriber-identifiable data and the supposed educational benefits of detailing generally. Sales representatives are trained to promote their products and influence doctors to increase the number of prescriptions written for their products. They are not trained to improve the prescribing practices of physicians based on treatment guidelines or best practices. *Cf.* Pet. 24. A statement from one company's marketing manual is telling. According to this company, when a doctor says "All my patients are controlled," that statement is an "obstacle" and sales representatives must find ways to handle it. That kind of training is not consistent with a description of detailing as providing doctors with "useful information."

3. Another ^{important} fact uncovered by Vermont – but not mentioned in the petition or the opinions below – is that petitioners and pharmaceutical companies *prohibit* publication or disclosure of prescriber-identifiable data. Petitioners' self-description as "publishers" of prescriber-identifiable data, Pet. i, 10, 12, is not accurate, because petitioners do not make prescriber-identifiable data publicly available. To the contrary, petitioners contractually bar disclosure of the data. Pharmaceutical companies license the right to use the data but are not allowed to disclose it to anyone else. In fact, it is undisputed that pharmaceutical companies prohibit sales representatives from disclosing information about a

doctor's prescribing practices *to the doctor*. *Sorrell*, 2009 WL 1098474, at *12 n.15.⁶

PhRMA's claim that prescriber-identifiable data is used to "facilitate" discussions thus represents a careful choice of language on its part. See PhRMA Br. 10. As described by the District Court in Vermont, a sales representative's use of the data is "covert." *Sorrell*, 2009 WL 1098474, at *11, *12. A former sales representative testified that he was trained not to show the data to doctors, to dismiss or deflect questions about the use of the data, and to understate the value of the data to the company's marketing practices. He explained that doctors "regard this information as confidential" so "we pretend we don't know." This same sales representative described making a sales pitch where he knew but did not disclose information about the doctor's prescribing practices. He called the presentation factually true but "very skewed" and "distorted." Whatever discussion is facilitated by prescriber-identifiable data, it is not an open exchange of information.

As this discussion shows, the record compiled in Vermont proves that pharmaceutical companies make

⁶ The First Circuit acknowledged that detailers "do not routinely disclose a physician's prescribing history to that physician" and "many physicians . . . never discover that the detailers possess such information." Pet. App. 23 n.6. But the record apparently did not disclose the fact that data mining companies contractually prohibit pharmaceutical companies from disclosing this information to doctors or anyone else.

secret use of prescriber-identifiable data to try to influence doctors without the doctors' knowledge. It is no surprise that the Vermont Medical Society,⁷ which provided strong support for Vermont's law, told the Vermont Legislature that "the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine." 2007 Vt. Acts & Resolves, No. 80, § 1, Finding 20, at 637.⁸

Even this cursory discussion of the proceedings and evidence in Vermont's case shows that the Court should not grant review at this time. New Hampshire's case was the first to raise this issue, and the speed of the proceeding came at the expense of the ordinary development of the record through discovery. One telling comparison is that the parties in New Hampshire conducted only a handful of depositions, while the parties in Vermont conducted almost 50. It makes little sense for the Court to grant review when the issue is still moving through the lower courts and other pending cases have more fully developed records.

⁷ The Vermont Medical Society represents two-thirds of Vermont doctors. 2007 Vt. Acts & Resolves, No. 80, § 1, Finding 20, at 637.

⁸ In addition to the Medical Society's resolution in the legislative record, Vermont also presented expert testimony on the ways that pharmaceutical marketing, including the use of prescriber-identifiable data, undermines the doctor-patient relationship.

C. Petitioners' lack of standing and the related uncertainty about the intended reach of New Hampshire's law further show that the Court should not grant review in this case.

The First Circuit's split decision shows that this case is procedurally complex. Petitioners' standing to raise all the First Amendment claims is doubtful. And uncertainty about the intended reach of New Hampshire's law – whether it applies solely to domestic conduct and, if so, what conduct – muddles the record for purposes of deciding the *Central Hudson* issue.

1. Petitioners' lack of standing clouds the First Amendment issues in this case.

As the majority opinion below recognized, this case presents a difficult question of standing. Pet. App. 12-17. The only parties interested enough to bring suit in New Hampshire were data mining companies. New Hampshire's law, however, principally regulates pharmacies, and the law has the effect of restricting the use of prescriber-identifiable data by pharmaceutical companies who market to doctors. No pharmacy, pharmaceutical company, or doctor felt sufficiently aggrieved to challenge New Hampshire's law. Vermont agrees with New Hampshire and the First Circuit that data mining companies do not have standing to litigate the rights of pharmaceutical companies, because those companies are fully capable of asserting their own rights. Indeed, PhRMA, the

trade organization for pharmaceutical companies, is a party to the litigation in Vermont.

The majority opinion below sets forth why petitioners lack standing and New Hampshire's Brief in Opposition convincingly explains why, as a result, this case does not present all the First Amendment issues asserted by petitioners. Rather than repeating those arguments here, Vermont notes only that this question of standing complicates any First Amendment review by this Court. PhRMA has filed an amicus brief with this Court that attempts to assert the views and interests of pharmaceutical companies. But no pharmaceutical company was concerned enough to file suit in New Hampshire. If the Court grants review in this case, the Court must first decide what issues petitioners have standing to raise – and the answer to that question may limit the Court's First Amendment review.

2. The record also shows uncertainty over the scope of New Hampshire's statute.

No court has definitively resolved the scope of New Hampshire's statute. In response to petitioners' facial Commerce Clause challenge, New Hampshire argued that the statute should be interpreted to "relate only to activity that takes place domestically." Pet. App. 48-49. Accepting this argument as a concession, the majority opinion construed the statute as not barring the routine out-of-state transfer,

aggregation, and sale of data from New Hampshire prescription records. Pet. App. 50. The court expressly did not decide "whether the purchasers [of the data] could subsequently make use of the aggregated data in New Hampshire." *Id.* at 50 n.11.

The filings in this Court, as well as the opinions below, show that this uncertainty also complicates review of the petitioners' First Amendment claims. Petitioners claim that "as construed by the First Circuit, [New Hampshire's law] permits most New Hampshire prescription history data to be used in detailing." Pet. 35. In fact the First Circuit did not go nearly so far. *See* Pet. App. 50 & n.11. However, Judge Lipez, dissenting on this issue, observed that the majority's interpretation may mean that the law "would pose no barrier to the use of such data by detailers *inside* New Hampshire." Pet. App. 146. Judge Lipez also highlighted a second, related issue not resolved by the majority opinion: whether New Hampshire pharmacies can transfer data out-of-state knowing the data will later be sold or used for marketing purposes. Pet. App. 146-48. New Hampshire, in its Brief in Opposition in this Court, argues that the statute should *not* be construed to allow New Hampshire pharmacies to avoid the restriction by routing data through out-of-state facilities.

Thus, as the case is presented to this court, there is no lower court decision that elucidates the reach of New Hampshire's statute. Instead, the petition, New Hampshire's response to the petition, and the separate opinions below demonstrate uncertainty on this

point. To reach the merits of petitioners' First Amendment arguments, the Court would likely have to first resolve this question and decide whether the First Circuit properly understood and applied New Hampshire's argument about the geographic reach of the statute. *Compare* Pet. App. 46-50 *with id.* at 142-50.

This uncertainty further illustrates the difficulty of resolving facial challenges and counsels against granting the petition. This Court is not in the best position to determine what concessions, if any, were intended by arguments made by the parties in the lower courts. Moreover, if arguments made below are deemed concessions that bind the parties in this particular proceeding, then the Court's First Amendment analysis may have little application beyond the specific facts of this case.

II. Vermont's record confirms that the First Circuit's decision is an unexceptional application of the *Central Hudson* test and absent a conflict in the circuits, there is no need for this Court's intervention.

Vermont's case is relevant for another, perhaps more important reason. It shows that the First Circuit's *Central Hudson* analysis is a reasonable and unexceptional application of the *Central Hudson* factors to a specific set of facts. Assuming New Hampshire's law warrants any First Amendment scrutiny as a restriction on speech – a point Vermont, like New Hampshire, does not concede – New Hampshire met its burden under *Central Hudson*.

Any doubt on this point is erased first, by Judge Lipez's separate and thorough analysis below, and second, by the recent decision upholding Vermont's similar law. The District Court in Vermont's case was not bound to follow the First Circuit's decision in *Ayotte*. Indeed, the District Court's decision shows its independent analysis, because the decision rejects *Ayotte's* first ground for upholding the law. *Sorrell*, 2009 WL 1098474, at *5-*6. The District Court conducted its own independent review, based on a substantial and detailed record compiled through nearly a year of pretrial proceedings, and readily upheld Vermont's law under *Central Hudson*. *Id.* at *8-*15.

Taken together, the First Circuit's ruling in *Ayotte* and the District Court's decision in *Sorrell* show that this Court's review is unnecessary and unwarranted. The lower courts are tasked with undertaking the detailed *Central Hudson* review in commercial speech cases. They have done so here and the decisions show that the relevant evidence strongly supports the constitutionality of these laws. Absent a conflict in the lower courts or a compelling indication that a lower court has erred, there is no need for this Court to review the application of established law to a particular set of facts. And, in fact, there is no pertinent split in the lower courts. The First Circuit's ruling fits comfortably alongside other lower court rulings upholding similarly limited restrictions on disclosure or commercial use of data. *E.g.*, *National Cable & Telecom. Ass'n v. FCC*, 555

F.3d 996, 1002 (D.C. Cir. 2009) (upholding restriction on disclosure of customer information); *Trans Union LLC v. FTC*, 295 F.3d 42, 53 (D.C. Cir. 2002) (upholding Gramm-Leech-Bliley privacy rules, including restriction on disclosure of consumer account numbers); *United States v. Miami Univ.*, 294 F.3d 797, 820-24 (6th Cir. 2002) (rejecting First Amendment challenge to Family Educational Rights and Privacy Act and finding no First Amendment right of access to student records); *Trans Union Corp. v. FCC*, 245 F.3d 809, 818 (D.C. Cir. 2001) (upholding restriction on the creation of targeted marketing lists under Fair Credit Reporting Act).⁹

Given this body of case law and the decisions in *Ayotte* and *Sorrell*, the lower courts may well continue to hold that laws restricting the use of prescriber-identifiable data are constitutional. If so, this Court's

⁹ Other laws restricting disclosure or use of data have apparently not been challenged, suggesting that petitioners greatly overstate the practical importance of the First Circuit's decision upholding New Hampshire's law. See, e.g., Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. § 1320d-6 (prohibiting use and disclosure of "individually identifiable health information"); Video Privacy Protection Act, 18 U.S.C. §§ 2710-2711 (prohibiting disclosure of "personally identifiable information concerning any consumer" of a video rental establishment without the individual's consent); Cable Communications Policy Act, 47 U.S.C. § 551(c)(1) (prohibiting disclosure of "personally identifiable information concerning any subscriber without the prior written or electronic consent of the subscriber"); Stored Communications Act, 18 U.S.C. § 2702 (restrictions on disclosure of electronic communications).

review will not be necessary. In any event, the Court should not take up the issue prematurely.

CONCLUSION

The petition for writ of certiorari should be denied.

Respectfully submitted,

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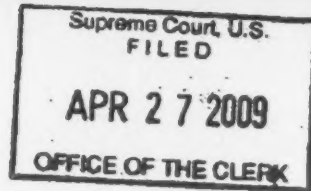
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No. 08-1202

IN THE
Supreme Court of the United States

IMS HEALTH, INC., and VERISPAN LLC,
Petitioners,

v.

KELLY A. AYOTTE, as Attorney General
of the State of New Hampshire,
Respondent.

**On Petition for a Writ of Certiorari
To the United States Court of Appeals
For the First Circuit**

**BRIEF OF WASHINGTON LEGAL FOUNDATION,
CATO INSTITUTE, REASON FOUNDATION,
THOMAS F. REILLY, BILL DEWEESE,
KEN GUIN, RAY MERRICK, AND GLENN RICHARDSON
AS AMICI CURIAE IN SUPPORT OF PETITIONERS**

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Date: April 27, 2009

QUESTION PRESENTED

Amici curiae address the following issues only, the first and second Questions Presented in the petition for certiorari:

1. To what extent does the First Amendment protect the acquisition, analysis, and publication of accurate factual information that is used by third parties for a commercial purpose?

2. Does the First Amendment permit a State to prohibit the acquisition, analysis, and publication of accurate factual information that is used by third parties for a commercial purpose, when the State does so for the purpose of "level[ing] the playing field" by reducing the effectiveness of the third parties' commercial speech, while simultaneously permitting the use of the identical information for communication of the State's preferred viewpoint?

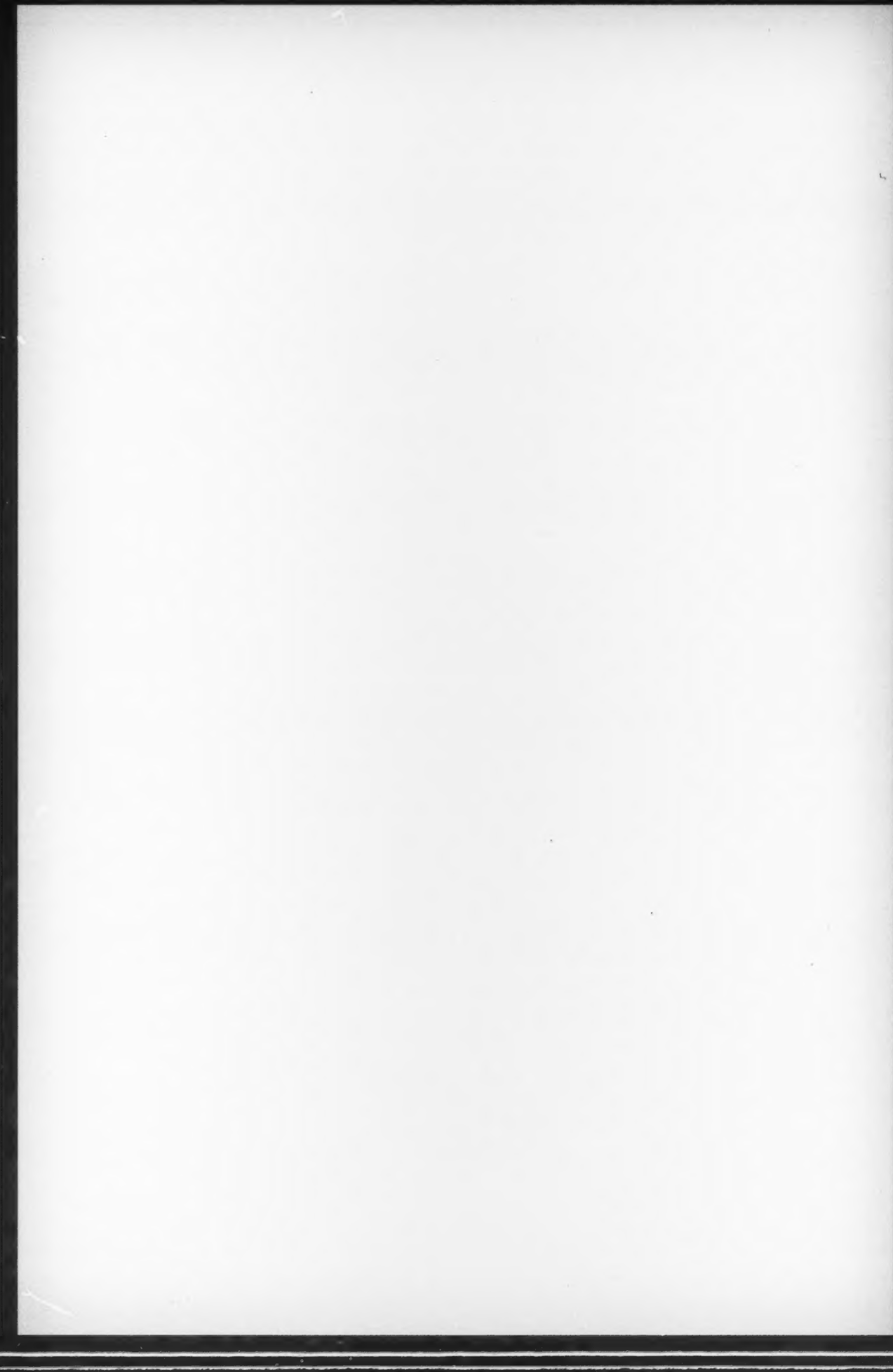


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**BRIEF OF WASHINGTON LEGAL FOUNDATION,
CATO INSTITUTE, REASON FOUNDATION,
THOMAS F. REILLY, BILL DEWEESE,
KEN GUIN, RAY MERRICK, AND GLENN RICHARDSON
AS AMICI CURIAE IN SUPPORT OF PETITIONERS**

INTERESTS OF AMICI CURIAE

Amici curiae are a bipartisan group of current and former elected state government officials, and three nonprofit organization; each strongly supports the First Amendment rights of participants in the health care industry to speak truthfully without unwarranted government interference.¹

The Honorable Thomas F. Reilly served as Attorney General of Massachusetts from 1999 to 2007. Rep. Bill DeWeese is the Majority Whip in the Pennsylvania House of Representatives and previously served as Speaker of the House. Rep. Ken Guin is the Majority Leader of the Alabama House of Representatives and serves as Chair of the House Rules Committee. Rep. Ray Merrick is the Majority Leader of the Kansas House of Representatives. Rep. Glenn Richardson is the Speaker of the Georgia House of Representatives. While recognizing the need to keep health care costs in check, each believes that

¹ Pursuant to Supreme Court Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than ten days prior to the due date, counsel for *amici* provided counsel for Respondent with notice of intent to file. All parties have consented to this filing; the parties indicated their consent in a letter lodged with the Court.

suppressing truthful speech is not an effective means of controlling costs and interferes with the exchange of information necessary to ensure medical advances.

The Washington Legal Foundation (WLF) is a nonprofit public interest law and policy center based in Washington, D.C., with supporters in all 50 States. WLF regularly appears before federal and state courts to promote economic liberty, free enterprise, and a limited and accountable government. In particular, WLF has devoted substantial resources to promoting free speech rights of the business community, appearing before numerous federal courts in cases raising First Amendment issues. *See, e.g., Nike v. Kasky*, 539 U.S. 654 (2003). WLF has successfully challenged the constitutionality of FDA restrictions on speech by pharmaceutical manufacturers. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000).

The Cato Institute was established in 1977 as a nonpartisan public policy research foundation dedicating to advancing the principles of liberty, free markets, and limited government. Cato's Center for Constitutional Studies was established in 1989 to help restore the principles of limited constitutional government that are the foundation of liberty. Toward those ends, the Cato Institute publishes books and studies, conducts conferences, publishes the annual Cato Supreme Court review, and files amicus briefs with the courts. This case is of central concern to Cato because it addresses the collapse of constitutional protections for commercial speech and the attempt by government to impede the free flow of information.

Reason Foundation is a national, nonpartisan, and nonprofit public policy think tank, founded in 1978. Reason's mission is to promote liberty by developing, applying, and communicating libertarian principles and policies, including free markets, individual liberty, and the rule of law. Reason promotes policies that allow and encourage individuals and voluntary institutions to flourish. Reason advances its mission by publishing Reason Magazine, as well as commentary on its websites, www.reason.com and www.reason.tv, and by issuing policy research reports that promote choice, competition, and a dynamic market economy as the foundation for human dignity and progress. Reason selectively participates as *amicus curiae* in cases raising significant constitutional issues, to further Reason's avowed purpose to advance "Free Minds and Free Markets."

Amici are concerned that by unduly restricting the dissemination of truthful information by Petitioners and others, the State of New Hampshire is relegating this important health care-related speech to a second-class status. *Amici* are also concerned that the decision below, if allowed to stand, sets a dangerous precedent that all but eliminates First Amendment restrictions on government efforts to "level the playing field" by favoring speech by one side of debate over speech by the other side.

STATEMENT OF THE CASE

Petitioners IMS Health Inc. and Verispan LLC are companies in the business of collecting and distributing health information, research, and analysis. Petitioners' reports provide detailed information

regarding individual physicians, their medical specialties, and their prescribing patterns. That information is immensely valuable to a wide variety of users. For example, researchers use the information as a means of locating doctors whose patients might be interested in participating in clinical trials of new medicines. The court of appeals explicitly found that Petitioners' "massive collections of information have great utility" for entities such as "educational institutions, public interest groups, and law enforcement agencies." Pet. App. 6.

The State of New Hampshire has become concerned by the commercial use of Petitioners' information by pharmaceutical companies. Those companies regularly engage in a practice known as "detailing," whereby a company salesperson (or "detailer") visits with doctors in an effort to persuade them to prescribe more of the company's brand-name (and thus, generally, higher-priced) drugs. It is widely recognized that these visits are more effective if the detailers come armed with information obtained from Petitioners - the information allows them, based on a doctor's prescribing history, to tailor their sales pitches in a manner likely to maximize prescriptions. Concerned that detailing was leading to increased prescriptions for high-priced drugs (and thus was causing significant increases in State health care costs), the New Hampshire legislature determined that it would take steps to control the effects of detailing.

The means devised by New Hampshire for controlling those price effects, however, was highly unusual. New Hampshire did not impose any direct controls on detailing. Instead, New Hampshire adopted

a statute, the Prescription Information Law (PIL),² which imposes restrictions on entities, such as Petitioners, that supply prescriber-identifiable information to pharmaceutical companies. New Hampshire's theory is that if pharmaceutical companies are denied access to prescriber-identifiable data, their detailing activity will be less successful in inducing doctors to prescribe higher-priced drugs, and thus State medical costs will be reduced.

The PIL provides, *inter alia*, that (subject to limited exceptions) no "prescriber-identifiable data" relative to prescription information may be "licensed, transferred, used, or sold" by any "pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose." N.H. Rev. Stat. Ann. 318:47-f. The PIL defines a "commercial purpose" as including, but not limited to, "advertising, marketing, promotion or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force." *Id.* Section 318:47-f has been construed by the appeals court as prohibiting Petitioners from conveying their prescriber-identifiable data to pharmaceutical companies for use in their detailing activities, but permitting Petitioners to convey the same data to others. Pet. App. 25.

² 2006 N.H. Laws 328, codified as N.H. Rev. Stat. Ann. 318:47-f & 318:47-g & 318-B:12, IV (2006).

Petitioners contend that the PIL, by imposing content-based restrictions on their rights to convey truthful information to others, violates their First Amendment rights. After conducting a trial, the U.S. District Court for the District of New Hampshire agreed, holding that the PIL did, indeed, violate Petitioners' First Amendment rights; it enjoined enforcement of the statute. Pet. App. 153-197.

The U.S. Court of Appeals for the First Circuit reversed. *Id.* at 1-151.³ The appeals court held that the First Amendment was completely inapplicable to Petitioners' claims because "the challenged portions of the statute principally regulate conduct, and to the extent that the challenged portions impinge at all upon speech, that speech is of scant societal value." *Id.* at 22. The court recognized that the PIL implicated First Amendment rights because of its impact on the detailing activities of pharmaceutical companies, but it determined that Petitioners lacked standing to assert those rights. *Id.* at 12-17.

As an alternative basis for its decision, the appeals court held that even if Petitioners' transfer of information to pharmaceutical companies were entitled to First Amendment protection, the PIL survives First

³ In addition to rejecting Petitioners' First Amendment claims, the First Circuit also rejected two other claims that the district court had not addressed: Petitioners' claims that the PIL was void for vagueness, *id.* at 42-46, and that it violated the dormant Commerce Clause. *Id.* at 46-50. One member of the panel dissented on the Commerce Clause issue; he would have remanded the case to the district court for an initial determination of the issue. *Id.* at 142-150 (Lipez, J., concurring and dissenting).

Amendment scrutiny under the standard established by *Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980), for evaluating restrictions on commercial speech. *Id.* at 26-41. In particular, the court held that the regulation of Petitioners' speech is "no more extensive than necessary to serve [New Hampshire's] interest in cost containment." *Id.* at 38. The court determined that one suggested alternative regulation that would not have entailed restrictions on Petitioners' speech – a counter-detailing program whereby New Hampshire would "educate doctors to prescribe low-cost generic drugs whenever possible" – "fails as a matter of simple economics." *Id.* at 39a. The court explained that the "the marketplace of ideas" lacked "equilibrium" because pharmaceutical companies spend \$4 billion each year on detailing, and New Hampshire and like-minded States are not equipped to (and thus should not be forced to) expend a similar sum to restore that equilibrium. *Id.* at 40. Thus, the Court held, New Hampshire did not violate the First Amendment – the State properly concluded that it could restore equilibrium only by imposing the PIL's speech restrictions on Petitioners (thereby, in New Hampshire's view, making detailing activities less effective in inducing prescriptions of expensive brand-name drugs). *Id.*

REASONS FOR GRANTING THE PETITION

The petition raises issues of exceptional importance. Although the PIL indisputably prohibits Petitioners from conveying information that is highly valued by its customers, the appeals court held that the PIL is altogether "outside the ambit of the First Amendment," explaining that the "challenged portions

of the statute principally regulate conduct, and to the extent that the challenged portions impinge at all upon speech, that speech is of scant societal value." Pet. App. 22. The appeals court likened Petitioners' speech to other forms of speech (*e.g.*, obscenity, libel, insulting or "fighting" words, and communications in furtherance of a crime) that according to the court lie "outside the compass of the First Amendment." *Id.* at 20. Review is warranted because the appeals court's conclusion that the PIL's prohibition against the transfer of information "principally regulates conduct" conflicts with numerous decisions of this Court and of other federal appeals courts. That conclusion threatens a radical curtailment of First Amendment rights by creating a previously unrecognized category of speech to which the First Amendment ostensibly does not apply.

As the Petition notes, laws similar to New Hampshire's have been adopted in two other States and, in light of the First Circuit's decision upholding the PIL, numerous other States are actively considering following suit. Review is also warranted in order to provide those States with guidance regarding the constitutionality of such statutes. It is highly unlikely that challenges to similar laws will reach the Court in the next several years; unless review is granted here, state legislatures will be confronted with proposals to adopt statutes similar to the PIL without any guidance from the Court. Moreover, this case is a particularly good vehicle for addressing the First Amendment questions presented by the Petition. The case has been brought by entities that supply information to the pharmaceutical industry; such entities are far better positioned than are pharmaceutical companies to raise First Amendment issues in a manner that will permit a meaningful merits resolution by the Court. In particular,

the PIL operates most directly against entities such as Petitioners who are in the business of transferring prescriber-identifiable data to consumers of such data (such as pharmaceutical companies). While the PIL creates difficulties for pharmaceutical companies by making it more difficult for them to obtain such data and thus has a significant impact on their ability to solicit customers, that impact is largely indirect in nature.

Moreover, such customer solicitation activity clearly constitutes commercial speech, a category of speech that has received somewhat less First Amendment protection than other forms of speech. While *amici* would welcome a reconsideration of the Court's downgrading of constitutional protections for commercial speech, it is far from clear that Petitioners' activity – conveying truthful information to customers for a fee – should even be deemed commercial speech. Petitioners thus have a far stronger claim that their speech is entitled to full First Amendment protection. Accordingly, it would make little sense to deny review in this case and await a challenge by a pharmaceutical company, when this case presents the strongest possible case for First Amendment invalidation of the PIL.

Review is also warranted because the First Circuit's alternative holding – that the PIL passes constitutional muster even if examined under a commercial speech lens – so clearly conflicts with this Court's commercial speech jurisprudence. In concluding that the regulation of Petitioners' speech met the fourth prong of the *Central Hudson* test (narrow tailoring), the appeals court rejected as infeasible several alternative regulations that would not have restricted Petitioners' speech – yet its grounds for doing so conflicted with decisions of this Court. In

particular, the appeals court held that New Hampshire was entitled to a "level playing field" – on which the State and pharmaceutical companies would have roughly equal influence over doctors' prescribing decisions – without having to pay the large sums that would be necessary to establish a comprehensive counter-detailing program. Pet. App. 39-40. On that basis, the appeals court determined that an expanded counter-detailing program did not qualify as a more-narrowly-tailored non-speech alternative regulation, because it would have cost New Hampshire too much to establish the "level playing field" it had a right to demand. *Id.* That determination conflicts with numerous holdings of this Court that a desire to create a "level playing field" among competing points of view does not justify imposing speech restrictions on the party with greater financial resources. *See, e.g., Buckley v. Valeo*, 424 U.S. 1, 48-49 (1976).

I. The Appeals Court's Holding That the PIL "Primarily Regulates Conduct" and Thus Lacks First Amendment Protection Conflicts With Numerous Decisions of This Court

The First Circuit found a simple way to avoid addressing all of the complex First Amendment issues raised by this case: it held that the PIL is altogether "outside the ambit of the First Amendment" because it principally regulates conduct, not speech. Pet. App. at 22. Review is warranted because the appeals court's characterization of Petitioners' information distribution as mere "conduct" is unprecedented under First Amendment law and conflicts with numerous decisions of this Court and other federal appeals courts.

The appeals court apparently arrived at its "conduct"

determination because it viewed Petitioners' data transfers as fundamentally different from "stereotypical commercial speech." *Id.* at 4. In characterizing Petitioners' activities, the court opined, "Unlike stereotypical commercial speech, new information is not filtered into the marketplace with the possibility of stimulating better informed consumer choices (after all, physicians already know their own prescribing histories)." *Id.* While the court was undoubtedly correct that Petitioners' information transfers do not resemble typical commercial speech (*e.g.*, Petitioners are not advertising their services or otherwise proposing a commercial transaction), that distinction suggests that Petitioners' activities constitute fully protected non-commercial speech, not that the activities do not constitute speech at all. The appeals court asserted that Petitioners' information transfers to pharmaceutical companies have "scant societal value," *id.* at 22, but that assertion is belied by the evidence at trial: pharmaceutical companies and other customers pay many millions of dollars every year for the information supplied by Petitioners.

As this Court has made clear, "the general rule is that the speaker and the audience, not the government, assess the value of information presented." *Edenfield v. Fane*, 507 U.S. 761 (1993). The appeals court can only be understood to have been saying that the information supplied by Petitioners was not being used wisely,⁴ not that the information lacked value. But such negative assessments regarding the uses to which truthful information will be put has never been deemed grounds

⁴ See, *e.g.*, *id.* at 4 ("[T]he societal benefits flowing from the prohibited transactions [*i.e.*, supply of information from Petitioners to pharmaceutical companies] pale in comparison to the negative externalities produced.").

for denying First Amendment protection. To the contrary, the Court has regularly condemned government efforts to prohibit "the dissemination of truthful information in order to prevent members of the public from making bad decisions with the information." *Thompson v. Western States Medical Center*, 535 U.S. 357, 374 (2002).

Remarkably, the panel held that the Act does not implicate IMS Health's First Amendment rights without citing a single case that so much as suggests that the publication of truthful data about individuals does not constitute First Amendment-protected speech. In fact, every prior federal appellate decision that has addressed the issue has concluded (or at least strongly suggested) that such publication is, indeed, protected by the First Amendment, regardless whether the published information is deemed a matter of public concern.

For example, the Court has stated that although it is a matter of public concern that the crime of rape has occurred, a mere list of the names of rapes victims is not a matter of public concern but rather is only a matter of "private concern." *Florida Star v. B.F.J.*, 491 U.S. 524, 536-37 (1989). The Court nonetheless held that the listing of such names by a commercial newspaper is speech entitled to substantial First Amendment protection and noted pointedly that "our decisions have *without exception* upheld the press' right to publish" information of only private concern. *Id.* at 530 (emphasis added).⁵ Similarly, the Court

⁵ Importantly, the appeals court did not base its decision on any asserted privacy rights of physicians, *id.* at 28, and thus that issue plays no role in this Petition. Judge Lipez explicitly rejected privacy concerns as a basis for upholding the PIL. *Id.* at 101 (Lipez, J., concurring and dissenting). Indeed, any privacy defense is

has upheld the First Amendment right of newspapers to publish the names of juvenile offenders (at least where it has lawfully obtained the names), even though States routinely treat such names as matters of private concern that should be kept confidential. *Smith v. Daily Mail Publishing Co.*, 443 U.S. 97, 104 (1979). Given that listing personal data constitutes "speech" when performed by commercial newspapers, there can be no grounds for stripping it of all constitutional protection simply because it is undertaken instead by other types of commercial entities, such as Petitioners.⁶

The Court has further made clear, in *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749 (1985), that First Amendment protections apply to

doomed to failure, given that New Hampshire disclaims an interest in preventing the dissemination of prescriber-identifiable data to anyone other than a drug company planning to use the data to assist with detailing. As the Court explained in *Florida Star*, States may not, consistently with the First Amendment, prohibit newspapers on privacy grounds from publishing rape victims' names unless they apply the prohibition across the board. *Florida Star*, 491 U.S. at 540. "When a State attempts the extraordinary measure of punishing truthful publication in the name of privacy, it must demonstrate its commitment to advancing this interest by applying its prohibition evenhandedly, to the smallest disseminator as well as the media giant." *Id.*; see also, *id.* at 541-42 (Scalia, J., concurring in part and concurring in the judgment).

⁶ Of course, the purposes for which speech is uttered may dictate the level of First Amendment protection to which it is entitled; e.g., commercial speech (that is, speech that "proposes a commercial transaction," *Bd. of Trustees v. Fox*, 492 U.S. 469, 473 (1989)) is entitled to a somewhat lesser degree of protection than other forms of speech. But a commercial purpose has never been deemed grounds for denying First Amendment protection altogether.

aggregated financial data regarding businesses disseminated for a profit by a credit reporting agency. In *Dun & Bradstreet*, the plaintiff alleged that unfavorable financial data disseminated by the credit reporting agency was false; it sued for libel. The only issue that divided the Court was the *degree* of First Amendment protection to which the credit reporting agency was entitled; all nine members of the Court agreed that agency's dissemination of aggregated financial data was speech that was entitled to *some* First Amendment protection. See, e.g., 472 U.S. at 759-60 (plurality opinion).⁷

In yet another factually analogous case, all nine Supreme Court justices indicated that regulation of dissemination of aggregated data should be deemed regulation of speech. *Los Angeles Police Dep't v. United Reporting Publishing Corp.*, 528 U.S. 32 (1999), involved plaintiffs who facially challenged a California statute that prohibited disclosure of police department arrest records to firms that refused to agree not to use those records for commercial purposes (e.g., sales to attorneys who were interested in soliciting business from arrestees). A majority of the Court rejected the facial challenge, finding that the First Amendment was not implicated when a government allows some citizens access to public records but denies access to others. But all nine justices agreed that if the plaintiffs could gain access to the records without government assistance, any government effort to prevent

⁷ The Court ultimately held that the First Amendment does not prohibit States from permitting the award of presumed or punitive damages in libel cases involving *wholly false speech* where (as in *Dun & Bradstreet*) the defamatory statements do not involve matters of public concern, even in the absence of a showing of "actual malice." *Id.* at 755-761 (plurality).

their use would implicate the First Amendment. See *United Reporting*, 528 U.S. at 40 (“This is not a case in which the government is prohibiting a speaker from conveying information that the speaker already possesses.”); *id.* at 42-43 (Ginsburg, J., with whom O’Connor, Souter, and Breyer, JJ., joined, concurring) (“Anyone who comes upon arrestee information in the public domain is free to use the information as she sees fit. [Once the information is published in a legal newspaper, the challenged statute] *would indeed be a speech restriction if it then prohibited people from using that published information to speak to or about arrestees.*”) (emphasis added); *id.* at 46 (Stevens, J., with whom Kennedy, J., joined, dissenting).

The panel arrived at its the-First-Amendment-is-not-applicable conclusion without even mentioning *Florida Star*, *Smith*, *Dun & Bradstreet*, *United Reporting*, or any of the numerous federal appeals court decisions that have concluded that dissemination of aggregated data is entitled to First Amendment protection. See, e.g., *TransUnion v. FTC*, 245 F.3d 809 (D.C. Cir. 2001), *cert. denied*, 538 U.S. 915 (2002). Review is warranted in light of the conflict between the decision below and the numerous decisions of this Court and other federal appellate courts regarding whether the transfer of aggregated data constitutes “speech” worthy of First Amendment protection.

II. Review Is Warranted Because This Case Is a Good Vehicle for Examining the Important First Amendment Issues Facing Numerous States Seeking to Control Health Care Costs

Review is also warranted because the issues raised in the Petition are arising with increasing frequency as

States look for novel ways to control their health care costs. As the Petition notes, two other States (Maine and Vermont) have adopted statutes substantially similar to the PIL; and following the First Circuit's decision upholding the PIL, numerous other States are considering similar legislation. Pet. 11. Review is warranted to provide those States with guidance regarding the constitutionality of such statutes. While litigation challenging the Maine and Vermont statutes is pending, the posture of those suits makes it highly unlikely that either suit could reach this Court for some years to come. Accordingly, if the Court is to provide any guidance to the more than 20 state legislatures that are considering similar legislation, it must come in connection with this Petition.

This case is a particularly good vehicle for addressing the First Amendment questions presented by the Petition. The case has already been tried in the district court, and the record is fully developed. The First Circuit addressed the merits of Petitioners' claims and determined that any First Amendment rights possessed by Petitioners are not infringed by the PIL. The appeals court directed entry of final judgment for New Hampshire, and thus there is no further opportunity for development of the record.

Moreover, companies (such as Petitioners) that collect and distribute prescriber-identifiable data are the entities best situated to raise all aspects of the First Amendment issues implicated by the PIL's speech prohibitions. Such companies are the ones most directly targeted by the PIL because they are the ones prohibited from transferring information to drug companies that would use the information to enhance their detailing capabilities. While the PIL may also infringe the First Amendment rights of drug companies, its impact on them

is largely indirect in nature – their ability to communicate with doctors is abridged only because they cannot obtain data from companies such as Petitioners. Accordingly, it would make little sense to deny certiorari for the purpose of awaiting a challenge to the PIL brought by a drug company; this suit already includes the plaintiffs most directly affected by the statute.

This case is a superior vehicle for addressing First Amendment issues implicated by the PIL because, in all likelihood, Petitioners' speech interests are entitled to significantly more First Amendment protection than are the speech interests of drug companies. When drug companies undertake detailing, they undoubtedly are engaging in commercial speech, a form of speech receiving a somewhat reduced level of First Amendment protection. Detailing meets the classic definition of commercial speech: speech (such as advertising) that "propose[s] a commercial transaction." *Fox*, 492 U.S. at 473. In contrast, Petitioners' activities do not so easily fit into the commercial speech mold. When Petitioners transfer information to a drug company, they are not proposing that the company engage in any sort of commercial transaction, and the transfer takes place "outside a traditional advertising format, such as a brief television or newspaper advertisement." *Nike v. Kasky*, 539 U.S. 654, 677 (2003) (Breyer, J., dissenting from dismissal of the writ). As Justice Breyer has explained, those noncommercial characteristics of speech by a business entity strengthen the entity's claim to heightened First Amendment protection. *Id.*⁸ Accordingly, if the Court

⁸ The Court has never suggested that speech not falling within the classic definition of "commercial speech" is nonetheless

is to consider First Amendment issues raised by the PIL, it makes much more sense to do so in the context of a challenge raised by Petitioners than in connection with a challenge raised by a drug company.

Several justices have expressed dissatisfaction with the Court's current approach to commercial speech cases, particularly where the speech at issue arises outside the context of traditional advertising and/or the government is seeking to restrict the speech for reasons other than its potential falsity. *See, e.g., Western States*, 535 U.S. at 377 (Thomas, J., concurring); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 517-18 (1996) (Scalia, J., concurring in part and concurring in the judgment). Given the context within which Petitioners' claims arise (speech arising outside of the traditional advertising context, with no suggestion that Petitioners' speech is false), this case would be an ideal vehicle for the Court to examine whether to modify existing commercial speech standards.

While it is true that the appeals court denied Petitioners' standing to assert the First Amendment rights of drug companies, that denial does nothing to detract from the attractiveness of this case as a vehicle for considering whether the PIL and/or similar laws pass First Amendment

entitled to reduced First Amendment protection simply because the speech arises in a commercial context. To the contrary, the Court has explicitly rejected the notion that a profit motive lessens the constitutional protection otherwise afforded to speech, stating, "Some of our most valued forms of fully protected speech are uttered for a profit." *Fox*, 492 U.S. at 482. *See also Consolidated Edison Co. v. Public Serv. Comm'n*, 447 U.S. 530, 537 (1980). The Court has, for example, afforded full First Amendment protection to the contents of a paid advertisement soliciting money. *New York Times Co. v. Sullivan*, 376 U.S. 254 (1964).

muster. For the reasons explained above, Petitioners' First Amendment claims are significantly stronger than the First Amendment claims of any drug company whose activities are affected by the PIL. Thus, First Amendment claims would not be significantly strengthened by combining the claims of Petitioners and a drug company in a single case. Petitioners' First Amendment claims are based on an asserted right to convey information to drug manufacturers, and those claims are not dependent on a showing that the PIL also interferes with drug companies' ability to communicate effectively with doctors.

In sum, this case presents an ideal vehicle for addressing First Amendment issues raised by state efforts to restrict speech that allows detailing to be effective.

III. The Appeals Court's Alternative Holding That New Hampshire May Restrict Speech in Order to "Level the Playing Field" Conflicts with This Court's Jurisprudence Regarding Commercial (and Other) Speech

Review is also warranted because the First Circuit's alternative holding – that the PIL passes constitutional muster even if examined under a commercial speech lens – so clearly conflicts with this Court's commercial speech jurisprudence.

The flaws in the First Circuit's commercial speech analysis are most evident in connection with its consideration of the fourth prong of the *Central Hudson* test: whether challenged regulation restricts speech no more than is necessary to further the governmental interest purportedly advanced by the regulation. *Central Hudson*,

447 U.S. at 556. The appeals court recognized, in accord with established case law, that a speech restriction does not survive this narrow tailoring test if the governmental interest would be equally well served by measures that do not involve regulation of speech: "Our starting point is well marked: 'If the First Amendment means anything, it means that regulating speech must be a last – not first – resort.'" Pet. App. 38 (quoting *Western States*, 535 U.S. at 373).

But the appeals court then proceeded to reject each of the non-speech measures suggested by Petitioners. In particular, it rejected a suggestion that New Hampshire adopt an expanded counter-detailing program, whereby state officials would seek to persuade doctors to prescribe low-cost generic drugs in place of the more expensive brand-name drugs being pushed by detailers. *Id.* at 39-40. It stated that a counter-detailing program would not accomplish New Hampshire's governmental interest in "restor[ing] equilibrium to the marketplace of ideas" in the absence of a multi-billion dollar expenditure designed to match the pharmaceutical companies' "marketing juggernaut": the over \$4,000,000 they spend per year on detailing. *Id.*⁹ The court reasoned that, in light of what it viewed as the prohibitive cost, a counter-detailing program was not an adequate substitute means for leveling the playing field. *Id.*

Review is warranted because the appeals court's level-the-playing-field rationale conflicts with numerous

⁹ The court earlier explained that New Hampshire sought "to level the playing field" by rendering detailing less effective "by eliminating the detailers' ability to use a particular informational asset – prescribing histories – in a particular way." Pet. App. 25-26.

decisions of this Court. In the context of campaign financing, the Court has repeatedly held that a desire to create a "level playing field" among competing points of view does not justify imposing speech restrictions on the party with greater financial resources. *See, e.g., Buckley v. Valeo*, 424 U.S. 1, 48-49 (1976). As *Buckley* explained:

[T]he concept that government may restrict the speech of some elements of our society in order to enhance the relative voice of others is wholly foreign to the First Amendment, which was designed "to secure the widest possible dissemination of information from diverse and antagonistic sources" and "to assure unfettered interchange of ideas for the bringing about of political and social changes desired by the people." ... The First Amendment's protection against government abridgement of free expression cannot properly be made to depend on a person's financial ability to engage in public discussion.

Id. (quoting *New York Times Co. v. Sullivan*, 376 U.S. at 266, 269). *See also McConnell v. Fed. Election Comm'n*, 540 U.S. 93, 227 (2003) (citing *Buckley*).

The Court recently observed that government efforts to restrict speech in order to "level the playing field" have "ominous implications," because they necessarily require the government to get into the business of evaluating the relative strength of speakers. *Davis v. Fed. Election Comm'n*, 128 S. Ct. 2759, 2773 (2008). The Court stated that it is up to the people, not the government, to make those kinds of determinations: "[T]he people in our democracy are entrusted with the responsibility for evaluating the relative merits of conflicting arguments'

and 'may consider, in making their judgment, the source and credibility of the advocate.'" *Id.* at 2773-74 (quoting *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765, 791-92 (1978)).

This Court's commercial speech case law includes nothing to suggest that the aversion to level-the-playing-field speech restrictions is reduced in the commercial speech context. To the contrary, the Court has repeatedly spoken out against government restrictions on commercial speech that are based on a government desire to protect listeners from their own misuse of too much speech. The Court has "rejected the notion that the Government has an interest in preventing the dissemination of truthful information in order to prevent members of the public from making bad decisions with the information." *Western States*, 535 U.S. at 374.

For example, in rejecting Virginia laws designed to protect consumers from too much drug-price advertising that might cause them to make unwise purchasing decisions, the Court explained:

There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not itself harmful, that people will perceive their own best interests if they are well enough informed, and that the best means to that end is to open the channels of communications rather than to close them. . . . Virginia is free to require whatever professional standards it wishes of its pharmacists; it may subsidize them or protect them from competition in other ways. But it may not do so by keeping the public in ignorance of the entirely lawful terms that

competing pharmacists are offering.

Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976).

If New Hampshire wishes to ensure that doctors receive what it deems a more-balanced presentation regarding the relative merits of competing prescription drugs, nothing prevents it from "open[ing] the channels of communication" by adopting an expanded counter-detailing program. But *Western States* and *Virginia State Bd. of Pharmacy* make clear that New Hampshire is not free to restrict the truthful speech of pharmaceutical companies (or, even worse, restrict the truthful speech of Petitioners and others who do not make any commercial pitches to New Hampshire's doctors) in an effort to "level the playing" field between itself and the pharmaceutical industry. It may fear that doctors will make unwise use of the information supplied to them by detailers, but such fears do not justify restrictions on truthful speech.

In sum, review is warranted because the appeals court's justification for upholding the PIL as a valid restriction on commercial speech – that it serves to "level the playing field" in terms of the quantity of speech reaching New Hampshire doctors – conflicts with this Court's jurisprudence regarding commercial speech and many other kinds of speech.

CONCLUSION

Amici curiae request that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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